DETERMINANTS OF ADHERENCE LEVELS TO ORAL PRE-EXPOSURE PROPHYLAXIS AMONG SERONEGATIVE PARTNERS IN HIV DISCORDANT HETEROSEXUAL RELATIONSHIPS

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DECLARATION

I, Samuel Mwangi Mwaura, do hereby declare that this thesis is my original work and has not been presented for the award of credit or any other degree to any other university/institution.

Signature…….. Date……..

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SUPERVISORS APPROVAL

This is to certify that this thesis has been submitted for examination with our approval as the University supervisors.

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DEDICATION

I dedicate this work to my wife, Esther Waithira, my son Ryan Mwaura and my entire family for their support, encouragement and prayers during my studies.

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I am grateful to God for this opportunity to pursue this Masters degree.

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LIST OF ABBREVIATIONS

ARV	Antiretroviral
ART	Antiretroviral Therapy
AIDS	Acquired Immunodeficiency Syndrome
CCC	Comprehensive Care Centre
FEM-PrEP	Preexposure Prophylaxis Trial for HIV Prevention among African Women
FDC	Fixed Dose Combination
FTC	Emtricitabine
FDA	Food and Drug Administration
HAART	Highly Active Antiretroviral Therapy
HBM	Health Belief Model
HIV	Human Immunodeficiency Virus
KNH	Kenyatta National Hospital
KNH-UoN ERC	Kenyatta National Hospital/University of Nairobi Ethics and Research Committee
MSM	Men who have Sex with men
NASCOP	National AIDS & STI Control Program
PrEP	Pre-Exposure Prophylaxis
PEP	Post Exposure Prophylaxis
PWID	People Who Inject Drugs
STI	Sexual Transmitted Infection
TDF	Tenofovir Disoproxil Fumarate
3TC	Lamivudine
UON	University of Nairobi
UNAIDS	United Nations Programme on HIV and AIDS
VOICE	Vaginal and Oral Interventions to control Epidemic
WHO	World Health Organization

ABSTRACT

Background: Adherence to PrEP medication is key for its efficacy in prevention of HIV infection acquisition by uninfected partner during high risk periods of HIV exposure. Some studies have demonstrated adherence to oral PrEP may be determined by lifestyle changes like excess alcohol intake, multiple sexual partners, frequent travels and frequency of sex. Other determinants of adherence to intake of PrEP includes employment, side effects of PrEP drugs, condom use and clinic accessibility.

Objective: The study was aimed at establishing determinants of adherence levels to oral PrEP drugs among seronegative partners in HIV discordant heterosexual relationships attending and registered at Mbagathi Hospital CCC.

Methodology: This was a cross-sectional design that applied two data collection methods: semi structured questionnaires guided interview and a checklist that was used during review of respondents' medical records. Both qualitative and quantitative data were collected. Convenience sampling method was used to get a sample size of 51 participants from about 60 HIV negative partners in serodiscordant heterosexual relationships who were taking oral PrEP. Data was analyzed using SPSS IBM statistics version 24 software. Both descriptive and inferential analysis were done. Descriptive analysis included the following; frequencies, percentages, means and standard deviations which were displayed in charts and frequency tables. Inferential analysis included binomial logistic regression and chi square statistical tests with a P value of ≤ 0.05 set as significant.

Results: A higher proportion of the respondents were females (52.9%) and male (47.1%). Most were self-employed (56.9%) with primary level of education (39.2%) and between 30-39 years age group (38%). Adherence levels assessed included; adherence to intake of oral PrEP pills (89.4%), adherence to time of taking PrEP (96%) and adherence to scheduled clinic appointments (80%). Male respondents were 1.01 times more likely to adhere to intake of PrEP pills than females. Maturity and higher education were associated with increased overall adherence to PrEP. (p=0.01). Longer period of being in HIV discordant relationship was associated with increased adherence to PrEP. (p=0.04). Use of condom after PrEP break was associated with increased intake of oral PrEP. (p=0.04). Those who engaged their partners in adherence support (80%) and had a plan of remembering to take their PrEP e.g. an alarm (58%) were found to have good adherence to intake of PrEP pills. (p=0.04). Increase in frequency of doing a HIV test was associated with increased adherence to intake of oral PrEP. (p=0.04). Majority (58.3%) reported side effects for the first two weeks after PrEP initiation, and presence of side effects was associated with reduced adherence to intake of PrEP pills. (p=0.003). Majority (98%) demonstrated good knowledge and understanding on use of PrEP which was associated with good overall adherence to PrEP. The respondents who engaged in extra marital sex (11.8%) (p=0.04) and those that used alcohol (19.6%) (p=0.05) were shown to have reduced adherence to intake of PrEP pills.

Conclusion and recommendations: The overall adherence for the different levels (intake, timing, appointments) was over 70%. The key determinants of the adherence observed were being male, being older in age, higher education, longer period of being in discordant status, partners support and higher frequency of HIV testing. However side effects of treatment, alcohol use and extra marital sex were associated with low adherence across all levels. The positive determinants of good adherence should be upheld and negative determinants should be addressed. In management of these clients there is need to look out for determinants that promote adherence that include maturity in age, level of education, length of being in discordant status and partners support. Programs should be initiated to create awareness on the effect of bad social habits like alcoholism and extra marital affairs. Laboratory services access should be strengthened in monitoring patients' adherence and side effects to treatment.

CHAPTER ONE: INTRODUCTION

1.1 Background

According to 2018 statistics released by UNAID data; indicated the total number of people living with HIV globally are about thirty seven million. The newly infected people with HIV were estimated to be about 1.8 million people every year and 940,000 AIDS related deaths were recorded by year 2017. There are about 5000 new HIV infections a day by 2017 globally, about 66% are in sub-Saharan Africa. The number of people living with HIV in Kenya is estimated to be about 1.5 million people. The total number of AIDS related deaths were 28,000 people and 53,000 people acquired new HIV infections by 2017 (Unaids, 2018).

In response to addressing the high incidences of new HIV infections reported globally; WHO in September 2015 released recommendations on use of oral PrEP drugs which aims at reducing the chances of HIV acquisition by the HIV negative individual when exposed to periods of high risk and exposure to HIV infection acquisition. (National AIDS & STI Control Programme (NASCOP), 2018).

According to WHO, oral PrEP is defined as provision of ARVs to individuals who are not infected with HIV during periods they are exposed to high chances of acquiring HIV infection (WHO, 2014).

Tenofovir Disoproxil Fumarate (TDF) 300mg and Emtricitabine (FTC) 200mg formulated as fixed dose combination are the current global recommended oral PrEP regimen for use as recommended by FDA in United States on July 2012 (McMahon et al., 2014). The current Kenya ART guidelines released in 2018 endorsed the same combination recommended by FDA as the preferred regimen for oral PrEP in the country. The guidelines also recommend use of TDF alone or combination of

the TDF and lamivudine (3TC) when the preferred regimen is not available. Thorough assessment of the client to include suitability and benefits of use, adherence readiness to both clinic appointments and drugs and lack of contraindications to any of the drugs should be performed before oral PrEP is commenced (NASCOP, 2018).

According to the Kenya 2018 ART guidelines the use of oral PrEP is recommended for the following categories of clients; seronegative partner in HIV discordant relationship especially when the couple is not using condoms during sexual engagement like when they want to conceive or when the viral loads of the seropositive partner are still detectable due to poor adherence to ART, resistance to ART or at the initial period of HAART commencement before 6 months of treatment to achieve viral suppression. Oral PrEP is also recommended for those people engaging in commercial sex, people who abuse and injects drugs, engaging in intimate sex when under influence of alcohol where condom use may not be negotiated, people who presents with habitual use of PEP and frequent STIs which indicates lack of condom use during sexual intercourse (NASCOP, 2018).

About 50 % of the HIV positive individuals in Southern and East Africa have been shown to be living in HIV serodiscordant relationship (Zheng et al., 2018). A study in Uganda showed that out of the married couples from the general population, about 5% to 7% were living in HIV discordant relationship (Zheng et al., 2018). Therefore if there is no intervention of HIV infection prevention among the HIV uninfected partners in serodiscordant heterosexual relationship, it will translate to high levels of HIV seroconversion which is estimated to be 3.7% to 19% annually (Zheng et al., 2018). In the foreword stated by the Kenya Director of Medical services; Dr. Jackson Kioko in the Kenya ART guidelines released in 2018 stipulates that, "HIV is a public health threat globally and in order to end AIDS by year 2030 as a Kenyan health objective, measures of HIV infection

prevention must be adopted in order to achieve a target of zero new HIV infections" (National AIDS & STI Control Programme (NASCOP), 2018).

WHO (2014) recommended use of oral PrEP as an addition intervention in HIV infection prevention strategies like use of condoms among the HIV uninfected partners in serodiscordant relationship which is categorized as a group with high exposure of acquiring HIV infection. The effectiveness of oral PrEP in clinical trial settings is directly associated with good adherence to oral PrEP by the clinical trial subjects (Desai et al., 2017). Several clinical trials in U.S. have demonstrated that the efficacy of oral PrEP is closely associated with adherence which determines reduction of risk of HIV infection acquisition (McMahon et al., 2014). Desai, et al (2017) concluded that of the two studies labelled VOICE and FEM-PrEP didn't demonstrate any benefit of PrEP due to poor adherence by the heterosexual women who were exposed to increased levels of acquiring HIV infection. Further studies are needed to determine whether the lack of efficacy in the two clinical trials above was as a result of poor adherence or was associated with other factors like physiological, population culture and behaviors (Curran et al., 2012). The efficacy rates of Oral PrEP ranges between 0-75 percent and these discrepancies could be attributed to poor adherence of the PrEP drugs prescribed (Haberer et al., 2013).

Use of oral PrEP was implemented in Kenya by 2016, and by the end of year 2017 the people who received PrEP at least once were 53,291 (Unaids, 2018). Oral PrEP is still in early phases of implementation, and less research has been conducted to study various factors that are attributed in realizing the effectiveness of oral PrEP by this unique group of serodiscordant couples (McMahon et al., 2014). McMahon et al (2014) concluded that oral PrEP will register effectiveness only to those heterosexual men and women in the US who have good adherence to the medication. However there have been no much research done in US about oral PrEP to establish the uptake

levels, acceptance by the community to use it, factors associated with its adherence, side effects experienced from use of oral PrEP drugs and change of sexual behaviors of the affected population (McMahon et al., 2014).

This study assessed determinants of adherence levels to oral pre-exposure prophylaxis among seronegative partners in HIV discordant heterosexual relationships attending Comprehensive Care Centre at Mbagathi hospital. It assessed demographic, social, attitude and behavioral factors of the study participants and side effects of oral PrEP drugs and their influence on the levels of adherence to oral PrEP intake, consistency in time of taking PrEP and adherence to scheduled clinic appointments.

1.2 Statement of the problem

The VOICE and FEM-PrEP which are the two major clinical trials ever conducted in Africa on PrEP efficacy in reducing HIV infection, showed no benefits of PrEP use, and lack of efficacy was attributed to poor adherence to PrEP with increased rates of side effects from the PrEP drugs (Van Damme et al., 2012), (Marrazzo et al., 2015).

Further studies are required to determine whether the lack of efficacy in the two clinical trials above was as a result of poor adherence or was associated with other factors like physiological, population culture and social behaviors (Curran et al., 2012), (Tobin, 2015).

The efficacy rates of oral PrEP ranges between 0-75 percent and these discrepancies could be attributed to poor adherence of the PrEP drugs prescribed (Haberer et al., 2013).

Oral pre-exposure prophylaxis use in Kenya is barely three years since implementation in 2016, therefore there is scarce information on adherence and determinants associated with oral PrEP use by the seronegative partners in HIV discordant heterosexual relationships. The same scenario of

scarce information on determinants of adherence levels to oral PrEP is replicated in the US (McMahon et al., 2014) .

This study therefore assessed three levels of adherence to oral PrEP on; adherence to PrEP drugs intake, time of taking treatment and scheduled clinic appointments. It also assessed the determinants of these adherence levels to oral PrEP among seronegative partners in HIV discordant heterosexual relationships attending CCC at Mbagathi Hospital.

1.3 Research justification

Good adherence is the major determinant of the effectiveness of oral PrEP drugs in preventing HIV infection transmission to seronegative partner by the seropositive partner when engaging in unprotected sex. By studying determinants of PrEP adherence levels on; adherence to intake of oral PrEP, adherence to time of taking PrEP and adherence to scheduled clinic appointments will inform on the clinic's PrEP program efficacy and outcome. This will generate more knowledge on HIV prevention strategies to this special group in alignment of achieving the global goal of zero new HIV infections by 2030.

1.4 Research benefits

The results generated from this study will demonstrate success rate and identify any gaps in the clinic's PrEP program. These will be used to strength health education sessions given to the clients hence improving overall quality of oral PrEP services by the healthcare providers in the clinic.

1.5 Research questions

1. What are the adherence levels to oral PrEP among seronegative partners in HIV discordant heterosexual relationships enrolled at Mbagathi Hospital CCC?
2. What are the determinants associated with adherence to oral PrEP among the enrolled HIV uninfected partners in HIV discordant heterosexual relationships at Mbagathi Hospital CCC?

1.6 Study Objectives

1.6.1 Main Objective

1. To establish oral PrEP adherence levels and their determinants among seronegative partners in HIV discordant heterosexual relationships attending Comprehensive Care Centre at Mbagathi Hospital.

1.6.2 Specific Objectives

1. To determine the adherence levels to oral PrEP among seronegative partners in HIV discordant heterosexual relationships enrolled at Mbagathi Hospital CCC.
2. To establish determinants of adherence to oral PrEP among the enrolled HIV seronegative partners in HIV discordant heterosexual relationships at Mbagathi Hospital CCC.

1.7 Limitation

The limitation that was encountered occurred during the data collection process because it was not possible to get rid of all the self-report bias on respondents' adherence to intake of PrEP pills, time of PrEP pills intake and scheduled clinic appointments. This was mitigated by use of a checklist to validate some of the information given by the respondents on their overall PrEP adherence from their clinic's medical records.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

One of the HIV infection prevention methods is the use of oral PrEP which is provision of ARVs to HIV negative individuals at a specific period of time when they are considered to be highly exposed to risk of contracting HIV infection. Currently Kenya ART guidelines of 2018 recommends use of TDF 300mg and FTC 200mg which is formulated as a fixed dose combination for use as oral PrEP in the entire country. Alternatively when the preferred regimen is not available or there is contraindication to FTC administration, TDF alone can be administered or combined with 3TC as fixed dose combination (NASCOP, 2018).

Adherence is key in determining successful outcome of PrEP administration. The access of PrEP medication is available in health facilities and programmes for PrEP administration differs from country to country. Individuals who qualify for PrEP administration should be able to access with ease and without experiencing stigma from these health facilities (Desai et al., 2017).

The United States of America (USA) have prioritized PrEP use among the individuals who abuse drugs which are administered through intravenous injections and sometimes with sharing of needles used, individuals who practice homosexuality and HIV negative individuals within heterosexual serodiscordant relationships (McMahon et al., 2014). McMahon et al (2014), concluded that since oral PrEP implementation program for HIV infection prevention in seronegative partners among heterosexual HIV discordant couples in US there have been few studies and research conducted on oral PrEP to determine its uptake by the community, the adherence levels of those initiated on oral PrEP, adverse effects reported by clients, physiological responses and how these individuals using oral PrEP adjust to their sexual behaviors which can put them at more risk of HIV infection acquisition. When oral PrEP medication is administered at

the correct time during periods with high exposure to HIV infection acquisition and there is good adherence to the treatment by the clients it will definitely minimize the risk of HIV infection acquisition hence slowing the spread of HIV. The use of TDF/FTC as oral PrEP is incorporated as a method of HIV prevention services which include correct and consistent use of condoms, HIV testing services, screening of sexually transmitted infections (STIs) and advocating for excellent adherence to PrEP medication. In US little attention has been given to research and study on determinants of oral PrEP and adherence levels of clients using oral PrEP among HIV negative individuals in serodiscordant heterosexual relationships (McMahon et al., 2014). Seronegative partners on PrEP are recommended to have quarterly HIV testing done. The use of oral PrEP will definitely lead to decreased condom use, hence poor adherence to the oral PrEP drugs will lead to high rates of HIV seroconversion. CDC embraced use of oral PrEP and included it in the US national guidelines in the year 2014. As a result, the challenges facing the program implementation are understudied since it is in its early phase of adoption (McMahon et al., 2014).

2.2 Statistics and Data

According to WHO statistics by end of 2017, "the estimated number of people living with HIV globally by year 2017 is about 36.9 million people. 21.7 million people globally were receiving ART by end of 2017 which translates to about 59%"(WHO, 2018).

According to UNAIDS statistics by end of 2017, adults prevalence rate of HIV globally between ages 15 to 49 years was estimated to be 0.8%. New HIV infection registered globally by end of 2016 was estimated at 1.8 million people and 1 million deaths were reported (Unaids, 2018).

According to WHO statistics, an estimated 25.7 million people in Africa are living with HIV and by end of 2017 about 15.4 million of them were already on HAART (WHO, 2018).

According to statistics by NASCOP (2018) about 1.5 million people are confirmed to be living with HIV infection in Kenya and 1,136,000 were already receiving ART by end of 2017 (National AIDS & STI Control Programme, 2018).

In sub Saharan Africa there are HIV serodiscordant couples and majority of index case are believed to be more men than women. Therefore majority of the campaigns towards HIV infection reduction in serodiscordant heterosexual relationships focuses more on men than women (Heffron et al., 2012).

A study that used a cohort of 27 groups with a total of 13,061 couples and demographic health survey data of 1,145 couples in 14 countries of sub Saharan Africa showed 47% of women in heterosexual HIV discordant relationship were seropositive which concluded that women are also likely to have equal chances like men to have seropositive status in serodiscordant couples (Eyawo et al., 2010).

2.3 Indications and Criteria for PrEP initiation

2.3.1 Indications

The Kenya ART guidelines of 2018 recommends use of oral PrEP by the seronegative partner in HIV discordant relationship in the following situations: during the period when the HIV discordant couple want to conceive hence engaging in unprotected sex, during the first six months of ART initiation to the seropositive partner before viral suppression is achieved to undetectable viral load levels and when the viral load of the infected partner remains high despite the seropositive partner been on ART probably due to poor adherence or resistance to ART. Oral PrEP is also indicated to HIV negative individuals who engage in sex with multiple partners of unknown HIV status, abuse injectable drugs where needles are shared, individuals who come for PEP repeatedly, recurrent

STIs an indication of engagement of sexual intercourse without the use of condoms and engaging in sex under the influence of alcohol where condom use cannot be negotiated (NASCOP, 2018).

2.3.2 Criteria

The recommended criteria by NASCOP before commencement of oral PrEP is to perform a HIV test to confirm the client's HIV status as negative by use of a rapid antibody test kit or ELISA method. The client should also not have symptoms that are suggestive of HIV infection like sore throat, fever, swollen lymph nodes with joint pains/headache and persistent diarrhea. The client should also be assessed his/her readiness to use oral PrEP with likelihood of good adherence to the treatment and clinic appointments. They should be educated on how to detect drugs side effects with actions to be taken and the importance of regular HIV testing every 3 months when their exposure to HIV infection still remains high (NASCOP, 2018).

2.3.3 Contra-indications to Oral PrEP

NASCOP recommends that oral PrEP should not be administered to this category of people: any individual who turns HIV positive after a HIV test or have signs and symptoms suggestive of HIV infection, adolescents who are below 15 years of age or have a weight of less than 35 kg, clients with renal impairment with a creatinine clearance of less than 50ml/min and clients suspected to have poor adherence to oral PrEP and follow up of clinic appointments (NASCOP, 2018).

2.3.4 Criteria for Discontinuing PrEP

According to NASCOP oral PrEP administration should be stopped when the client taking oral PrEP turns HIV positive, if there is a renal function impairment with a clearance rate of less than 50ml/min, when the exposure to risk of acquiring HIV infection is minimized or stopped, when the client is not able to adhere to oral PrEP treatment and clinic follow up, when the client voluntarily requests to stop taking oral PrEP and when viral suppression of the seropositive partner

in serodiscorant relationship is achieved to undetectable viral load levels and the couple is also using condom when engaging in sexual intercourse (NASCOP, 2018).

2.4 Adherence to oral PrEP

Adherence to oral PrEP is very vital for effectiveness of the oral PrEP to be realized during the period the client is considered to have an increased exposure of acquiring HIV infection, hence good adherence to oral PrEP by the HIV negative partner will result in preventing transmission of HIV infection to HIV negative individuals by HIV positive partners in serodiscordant heterosexual relationships. Since the administration of oral PrEP as a method of HIV infection prevention was rolled out in 2014 in US and is in early phases of adoption globally, few studies and research on determinants of adherence levels have been conducted (McMahon et al., 2014).

WHO description of good adherence to oral PrEP is when the client commenced on oral PrEP is able to take about 4 to 7 doses on average per week which is adequate dose to protect them from acquiring HIV infection during the periods that they are highly exposed to HIV infection (WHO, 2014).

When a couple find themselves in a HIV discordance status it creates a dilemma to be addressed by the two individuals so that they can maintain intimacy in their relationship. This dilemma of HIV serodiscordance may promote increased adherence to PrEP drugs than other groups of people who qualify for PrEP indication like MSM and people who inject drugs. Some studies in US have demonstrated individuals in HIV serodiscordant heterosexual relationship do not embrace correct and consistent use of condoms hence putting the HIV negative individual in these relationships into more risk of contracting HIV infection from the HIV positive partner (McMahon et al., 2014).

A study done in Kenya at Thika between March to July 2011 demonstrated willingness of taking PrEP drugs by HIV uninfected individuals in serodiscordant sexual relationship, 90% of them indicated they were willing to take PrEP on long term basis, however side effects experienced when taking PrEP drugs was their main concern (Heffron et al., 2012). This study was actually conducted before implementation of oral Prep in Kenya, so the concerns raised were based on assumptions rather than the real concerns currently experienced by the individuals taking medication of oral PrEP.

HIV physiology of transmission is the same worldwide, but adherence of antiretroviral cannot be replicated in different populations of the world. Adherence levels varies in different studies, and may be determined through self-reporting, pill count and blood drug concentrations. Adherence to PrEP can be categorized as high, moderate and low based on drug concentration measured from different blood samples. When a client on oral PrEP is able to take one or two tablets of PrEP in 7 days it is enough to detect the drug in blood samples taken. Individuals with high drug adherence are classified as having more than 70% drug blood levels, moderate adherence as 41-70% and low adherence as 40% and below (Desai et al., 2017).

The World Health organization (WHO) in 2014 held a meeting to discuss matters related to PrEP adherence. From that meeting it was alluded that there is no specific way to determine adherence to oral PrEP. However various methods of adherence measurement were recommended which may include: clients on oral PrEP declare to the health care provider whether they are taking the medication as prescribed which is known as self-reporting which may be augmented with short message service surveys, where the client sends an SMS to the health facility anytime they take their pills, the pills refill data from the pharmacy will indicate whether the clients adhered to clinic appointments rather than whether they really swallowed the pills, monitoring through electronic

devices which sends a signal to the health facility system anytime the pill container is opened, and monitoring of drug levels in plasma, red blood cells and hair (WHO, 2014).

Other factors that may influence adherence of PrEP include drugs affordability, feasibility, compatibility with users' lives and selection of a good method to monitor PrEP pattern of use accurately (WHO, 2014).

2.5 PrEP, Contraception and Pregnancy

Studies have indicated that PrEP drugs don't reduce effectiveness of contraceptives when administered together, and contraceptives also don't reduce PrEP medication efficacy. Data also indicate that oral PrEP don't interfere with pregnancy when taken by gravid women. HIV infection risk increases during pregnancy hence good prevention measures of HIV infection should be advocated like use of PrEP with good adherence (Desai et al., 2017).

2.6 Levels and Determinants to oral PrEP adherence.

There are a number of factors attributed to PrEP adherence by HIV uninfected individuals in serodiscordant heterosexual relationships. A study conducted in Kenya a site at Thika by Curran et al which analyzed 96 HIV uninfected individuals sexual behavior change and adherence to PrEP through use of short messaging service (SMS) concluded that majority of participants estimated at about 96.9% demonstrated taking oral PrEP more than 80 % of the days, but 69.8 % reported missing at least one dose. Participants who reported engaging in sex without condom at least once were about 47.9%. There was no correlation of unprotected sex with PrEP use. They also found out that those participants who were engaging in sex regularly had high levels of PrEP adherence than those who had sexual abstinence" (Curran et al., 2012).

Another study conducted in Kenya focusing on oral PrEP administration to homosexual men in Kilifi and Kangemi sites, concluded that lower adherence to PrEP was influenced by transactional sex, frequent travels and prolonged period of PrEP use. However participants who had good source of income had a higher adherence than the unemployed participants. Analysis recommends that in order to address the adherence challenges the following should be addressed: sex work, mobility and prolonged PrEP use. The challenges of frequent travel can be addressed by having PrEP distributed in the entire country for ease of access anywhere in the country. Stigma, depression and risk perception may also influence PrEP adherence (Mugo et al., 2015).

A study conducted in South Africa which was investigating the seroconversions rate in women enrolled in a clinical trial who had low adherence to oral PrEP concluded that the following factors associated with poor adherence lead to seroconversion which was recorded: participant who were below the age of 35 years, those who had less than 2 children, those who were single and were not cohabiting and those who got a new sexual partner during the study period. The study concluded that lack of good adherence to oral PrEP was observed as a major barrier to successful prevention of HIV infection (Wand and Ramjee, 2017).

2.7 Theoretical Framework

One of a successful theoretical model which can be used when addressing adherence to oral PrEP, is the Health Belief Model (HBM). The HBM describes some of the behavioral factors adopted by individuals towards improving their health through change of attitudes and beliefs. The model was developed by some psychologist in US who tried to understand why a national free tuberculosis screening program was not successful by studying the health beliefs and attitudes of the community towards the failed program in 1950s. This model since then has been adopted in understanding various community behaviors, beliefs and attitudes related to their health well-being

in both short and long term medical conditions (University of Twente, 2017). According to University of Twente, the HBM is composed of six main constructs which are described as follows: The individual worries about getting a disease condition, they contemplates about the severity or the seriousness of that disease, they consider the benefits of following the advice given by the health care provider in addressing and treating the disease, they evaluate the cost associated with following the advice and some of the factors that may hinder them from embracing the advice, they identify ways of helping them to raise awareness of the disease and finally they put more efforts of improving their health status by taking an action (University of Twente, 2017).

The application of this model in Oral PrEP program will be based on understanding the importance of adherence to oral PrEP drugs to prevent HIV acquisition by the seronegative partner in HIV discordant heterosexual relationship (Chizi, et al., 2014). According to this model, an individual will adopt behaviors to protect them from the risk if there is a perceived health risk. Sometimes an individual may make faulty decisions to avoid the risk that may even place them at an increased risk for developing adverse health conditions. The person will assess their vulnerability to get a condition and the severity of that condition hence will adopt health promoting behaviors based on the outcome of weighing the situation impact on the cost and the benefits. The person will express confidence of their ability to adopt the recommended behavior and HBM calls this self-efficacy (Chizi, et al., 2014).

However some studies have shown that a HIV negative individual may perceive the increased chances of HIV infection acquisition but still appear to doubt their future risk hence endangering themselves by participating in actions that make them more prone to HIV acquisition in contradiction of the HBM (Chizi, et al., 2014).

Chizi et al (2014) summarized the HBM as integration of the following factors in normalizing the health status of individuals when they are sick: the individual gets an urge or incentive to change their behavior. They evaluate the risk associated if they don't change their old behaviors, they consider the benefits that will result from the change of behavior and balance them with the barriers expected to be encountered during the behavior change process, the individual gains confidence with the mode adopted of behavior change which is referred to as self-efficacy and finally the individual will take an action to change the behavior like having some counselling sessions or watching a TV program discussing the said behavior change (Chizi, et al., 2014).

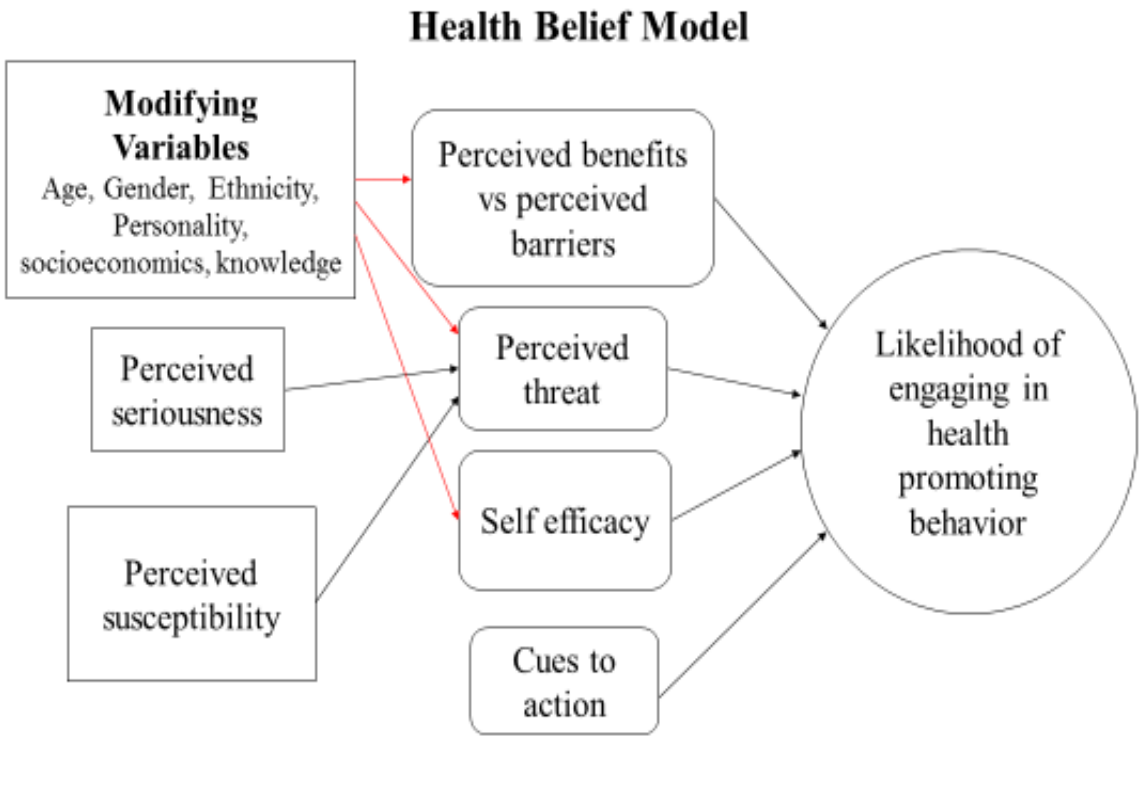

Figure 1: Theoretical framework

2.8 Conceptual Framework

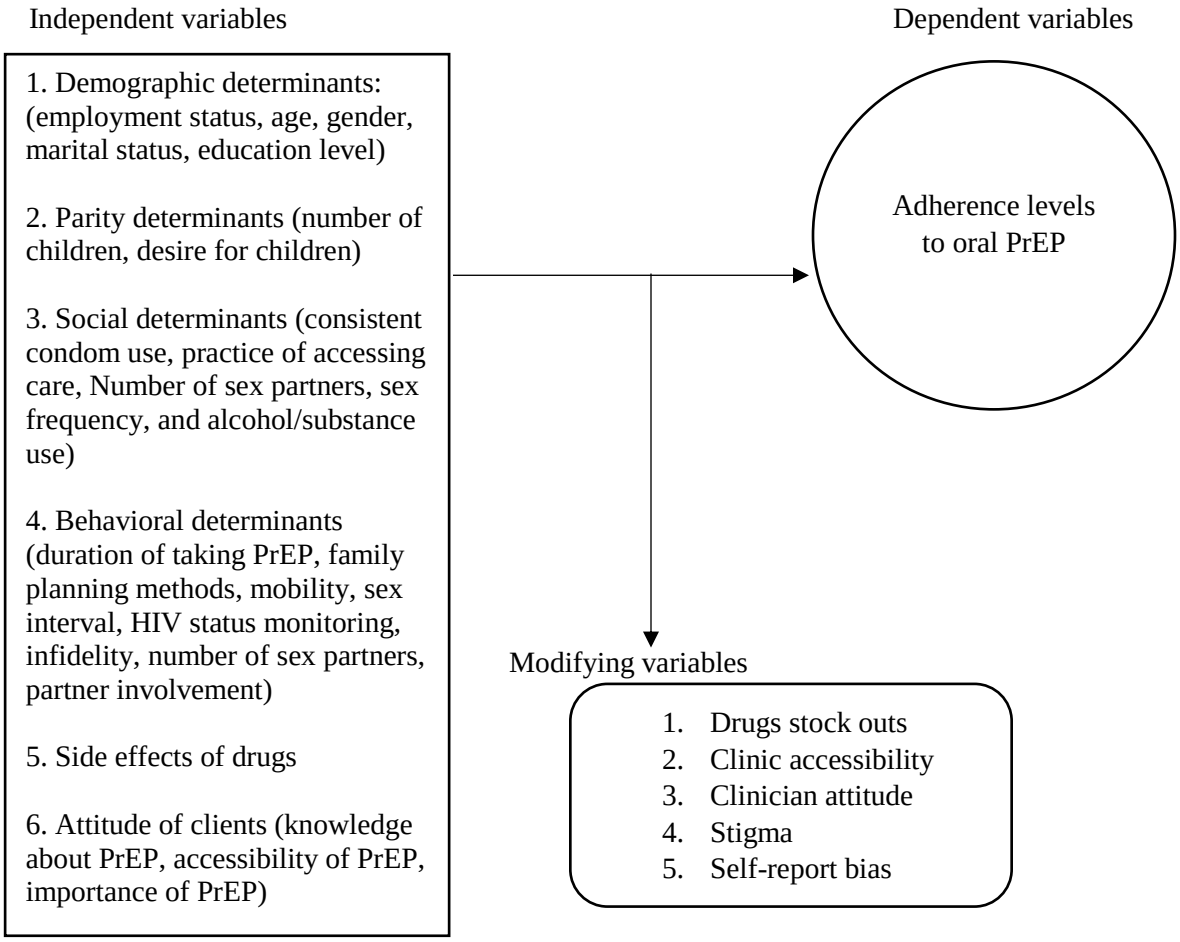

Figure 2: Conceptual framework

Adherence to Oral PrEP is dependent on whether there is perceived risk of HIV infection by the client. Oral PrEP is not administered for the entire life unlike the ART taken by the seropositive partner. The period that the seronegative partner is highly exposed to HIV infection is the only time that they will be on the oral PrEP therapy. This is the period when they are not using other prevention methods of HIV infection. Efficacy of oral PrEP is directly linked with good adherence state. Easy accessibility and provision of oral PrEP freely have increased uptake of oral PrEP in Kenya since the time the program was rolled out in 2016 (National AIDS & STI Control Programme, 2018). Stigma have a negative influence on adherence because clients feels if they

are seen taking oral PrEP by friends or relatives, an assumption will be made that they are HIV positive since they are already taking ARVs. Oral PrEP when combined with other modalities of HIV infection prevention like consistent condom use will increase its efficacy in reducing seroconversion prevalence rates by the seronegative partner in a serodisordant relationship. For couples who wish to conceive there will be low or no condom use hence oral PrEP remains the only method of HIV infection prevention, so good adherence is key to prevent seroconversion (Wanjiru et al., 2014).

Personal factors infringing on clients' lifestyle like excess alcohol intake, injectable drug abuse, multiple sexual partners, engaging in transactional sex are all attributed with increased HIV infection since some may interfere with the intellect judgement when engaging in sex and also reduce adherence to PrEP drugs hence increasing risk of seroconversion of the seronegative partner in the serodiscordant heterosexual relationship. Serodiscordant heterosexual couples may register high adherence levels as compared to other groups of people that qualify for PrEP like MSMs and PWIDs. HIV seronegative women who are pregnant and in serodiscordant heterosexual relationships are at a period where they have increased chances of acquisition of HIV infection due to their reduced immunity so they should be encouraged to correctly and consistently practice use of condoms during sexual intercourse and use of oral PrEP with good adherence should be advocated. Couples who have sex regularly have high levels of PrEP adherence than the couples who abstain. Frequent travels are associated with poor adherence due to the change of environment where couples can experience stigma or lack of easy access to oral PrEP. Other factors that may influence oral PrEP adherence are age of the couple, number of children and marital status (Curran et al., 2012)

Economic factors have also a role in adherence because it have been shown those clients who are employed have good adherence to oral PrEP than the unemployed ones (Zheng et al., 2018).

Oral PrEP drug factors like side effects will deter good adherence, hence some clients may opt out completely from the oral PrEP program or reduce their adherence levels especially when the adverse effects are severe. There is no standard method of monitoring adherence to oral PrEP, hence several methods have been employed like self-reporting, pill count, pharmacy refill data and blood drug concentration. However despite the obvious bias in self-reporting, it remains the most efficient, fast and cost effective method of monitoring oral PrEP adherence (WHO, 2014) .

Clinic factors have also a direct link with oral PrEP efficacy. Excellent client handling if possible by one clinician in the clinic to initiate oral PrEP and do subsequent clinic follow up visits to enhance on adherence counseling and monitoring for side effects will yield better results of oral PrEP efficacy than when the client meet a different clinician every time they visit the clinic (WHO, 2014) .

CHAPTER THREE: METHODOLOGY

3.1 Study design

A cross-sectional descriptive design was adopted for this study.

3.2 Study area: Mbagathi Hospital Comprehensive Care Centre

Mbagathi Hospital was built in 1950s as an extension to King George VI Hospital currently known as Kenyatta National Teaching and Referral Hospital for isolation of infectious diseases like tuberculosis, measles, meningitis and leprosy, hence it was originally known as Infectious Diseases Hospital (IDH).

In 1995 IDH was made an independent institution and transformed into Mbagathi District Hospital (Otieno D., 2010).

The hospital is located at Kenyatta Golf Course, Mbagathi Way in Nairobi County, Lang'ata Sub-County. It borders Kenyatta National Hospital (KNH), Kenyatta City Council market, Defence Forces Memorial Hospital (DFMH), Kenya Medical Research Institute (KEMRI) and the densely populated Kibra slums.

It is currently managed by Nairobi County as a Level 4 Hospital with one of the largest catchment area of about one million people, mainly comprising of the urban poor. It is easily accessible and offers affordable healthcare services. It provides curative, preventive, promotive and rehabilitative healthcare services to all Kenyans. It offers both outpatient and inpatient services with a bed capacity of about 200 beds. It plays a major role in decongesting KNH which should be dealing with referral cases only.

Mbagathi Hospital Comprehensive Care Centre is a department of the hospital which gives comprehensive HIV care services with about 4,851 active registered clients and 4,828 clients on

treatment. The clinic offers free services to all the clients. It serves cosmopolitan nature of clients supported by good infrastructure, good documentation and record keeping practices to support quality data abstraction. The clinic operates Monday to Friday from 6.30am to 3pm. It is usually closed on weekends and public holidays.

The CCC also serves the HIV discordant couples with about 200 active serodiscordant couples registered. It offers comprehensive counselling to discordant couples, HAART to seropositive partners, oral PrEP to seronegative partners and other HIV prevention methods like condom dispensation. About 60 clients who are seronegative partners in HIV discordant relationships are currently on oral PrEP. The oral PrEP program is run with partnership of Kenya Medical Research Institute - Centre for Clinical Research (KEMRI CCR) and Partners in Health and Research Development (PHRD) currently involved in many clinical trials on oral PrEP use in discordant couples.

3.3 Study Population

The study population was composed of all the 60 HIV negative partners in serodiscordant heterosexual relationships above the age of 18 years registered at Mbagathi Hospital Comprehensive Care Centre who were enrolled and taking oral pre-exposure prophylaxis (PrEP).

3.4 Sample size and sampling criteria

The sample size was obtained by use of the formula below for calculating sample size for cross sectional studies/surveys (Charan and Biswas, 2013)

$$\text{Sample size} = \frac{Z_{1-\alpha/2}{}^2 p(1-p)}{d^2}$$

Sample size =1.96 x 0.07(1-0.07)/0.05^2 = 51 (Charan and Biswas, 2013)

Where:

Z represents: standard normal variate (at 5% type 1 error (P<0.05) it is 1.96 (Charan and Biswas, 2013)

P represents: Expected proportion in population based on previous studies or pilot studies - 7% (Zheng et al., 2018).

d represents: Absolute error or precision (5%) (Charan and Biswas, 2013)

Sampling:

Convenience sampling method was used to get the study sample.

3.5 Ethical Considerations

Ethical approval to conduct the study was sought from KNH/UoN Ethics and Research Committee. Permission to access the study population was sought from Mbagathi Hospital administration. Informed consent was signed by the 51 study respondents.

The right to privacy and confidentiality of the study participants was maintained at all the stages of the study. This was achieved by not using participants' names in the questionnaires rather use of serialization and generation of unique codes. The data was stored using unique identifiers for any future reference or requirement.

Any HIV uninfected participant in serodiscordant relationship was entitled to full HAART initiation in case of seroconversion in the course of the study.

3.6 Inclusion criteria

The participants interviewed met the following criteria:

- They were in a HIV serodiscordant heterosexual relationship.
- They were the HIV negative partners in a serodiscordant relationship.
- They were above 18 years of age.
- They were enrolled and attending the oral PrEP program.
- They were taking oral PrEP medication.
- They were registered in Mbagathi Hospital CCC HIV serodiscordant database.
- They gave informed consent before participating in the study.

3.7 Exclusion criteria

The participant who were excluded from the study:

- Failed to give informed consent.
- Their updated medical records were missing.

Those who transferred out from Mbagathi Hospital CCC to other similar health facilities

3.8 Study Instruments

The data collection tools used included a semi-structured questionnaire which was used to interview the participants and a checklist for extracting data from their clinic's medical records.

Data was obtained from the sampled HIV negative partners in serodiscordant heterosexual relationship through interview process using a semi structured questionnaire which guided the interviewer on the flow and questions to ask. The interviewer recorded the feedback and the responses given by the study participants in the questionnaires. The clinic's medical records database was the source of the secondary data which was used to fill the checklist with the medical data and also used to clarify and validate some information given inaccurately by the study participant.

3.9 Management of Data

3.9.1 Data Collection

The 51 study participants were identified and recruited within a period of two weeks from a total of about 200 serodiscordant couples registered in the clinic. A total of 60 HIV negative partners who were taking oral PrEP treatment and were on follow-up were identified among the serodiscordant couples registered in the clinic. Since not all the HIV negative partners in discordant relationships visiting the clinic were on oral PrEP, the investigator used convenience sampling by identification of the seronegative partners who were taking and enrolled in oral PrEP programme with the help of the clinic's staff. The recruited study participants were assessed by the investigator whether they met the other criteria listed in 3.6 above.

An average of 5-7 participants were interviewed per day. The investigator explained to the study participant in details using either English or Kiswahili based on the identified study participant preference the following; the purpose of the study and their rights as study participants using the information contained in the consent form in appendix I as a guide. When the study participants understood what the study entailed and they agreed to participate in the study voluntarily they eventually signed the consent form. The investigator was assisted by two research assistants to conduct the interview process after signing the consent form with the participants.

3.9.2 Interview process

The interview was conducted guided by the questionnaire in appendix II. The interviewer used either English or Kiswahili language based on the study participant preference. The interviewer systematically interviewed the study participant guided by the questions in the questionnaire and filled in all the responses given by the study participant in the questionnaire. A checklist in appendix III was used to get the secondary data which was extracted from the study participants'

clinic's medical records. The interview process took about 15 to 20 minutes and on completion the investigator/interviewer appreciated the participant for willingly accepting to be interviewed and providing their information to be used in analyzing the study findings. The filled questionnaire and the checklist with the secondary medical data of the study participants were serialized to generate a unique code which was used for data analysis process.

3.9.3 Pretest study

A pretest study of 5 participants was conducted at Mbagathi Hospital CCC before commencement of the main study within a period of 2 days which determined the reliability and validity of the questionnaires in generating the data required to answer the research questions. Reliability test conducted was checking on the consistency of the data generated from the questionnaires when the two research assistants and the investigator interviewed the respondents. Validity test was conducted by comparison of self-report on PrEP adherence by the respondents with the documented self-assessment adherence already recorded in the respondents' clinic's medical records.

3.9.4 Research assistant training

A detailed 3 days training of the research assistants was conducted before the study participants' recruitment. This equipped the research assistants with knowledge about the entire study objectives and the questions that the study was seeking answers to, the study participant recruitment process, the rights of the study subjects, content of the questionnaires, checklist and how to fill in the responses accurately and the data analysis process.

3.9.5 Data processing and analysis

After completion of data collection, all questionnaires and checklists were verified. Data cleaning was conducted by identification of incomplete, incorrect, inaccurate or irrelevant parts of the data. This was followed by replacement, modification or deletion of the incomplete and inconsistent data.

With the assistance of a stastician the data collected was entered into SPSS IBM statistics version 24 software and categorized into the following: demographic data, social and behavioral data, side effects of the drugs and clients attitudes. Data was analyzed using SPSS IBM statistics version 24 software.

Statistical tests of significance like binomial logistic regression and Chi square were used to test the influence of the following determinants on PrEP adherence levels; PrEP drugs side effects, respondents' demographic factors, respondents' knowledge and attitude towards PrEP and social lifestyle of the respondents. The significance level was set at a P value of ≤ 0.05.

With the assistance of the stastician qualitative data was transcribed after reading the filled questionnaires severally and understanding the study participants' responses to various questions. A framework for coding the transcribed data was developed which enhanced structuring and labelling of the data. The coded data was analyzed through identification of themes and looking at the patterns of questionnaire responses. A conclusion was derived from the analysis of the study findings.

3.9.6 Data storage and dissemination of research findings.

The questionnaires and the consent forms were stored securely in a locked file cabinet by the investigator. The computer data files were compressed and encrypted before storage in the hard disk.

The findings of this study was disseminated through presentation to School of Nursing UoN. A presentation of study findings was done to Mbagathi Hospital administration. The Mbagathi Hospital CCC staff promised to use the study findings to educate the clients on interventions taken to address their adherence gaps to oral PrEP as adopted from the study findings.

A study report was also submitted to KNH/UoN ERC for their review and repository.

A presentation of the study report in form of hard and soft copy was given to the UoN library for thesis repository. The investigator desire to publish the study findings therefore a manuscript was prepared for publishing in one of the medical journals with competitive peer review.

The investigator also desire to present the findings of the study to NASCOP and oral PrEP program sponsors Kenya Medical Research Institute - Centre for Clinical Research (KEMRI CCR) and Partners in Health and Research Development (PHRD) to inform them on adherence levels and some of the determinants of adherence to oral PrEP at Mbagathi Hospital CCC.

CHAPTER FOUR: RESULTS

4.1 Introduction

The purpose of this study was to assess determinants of adherence levels to oral pre-exposure prophylaxis among seronegative partners in HIV discordant heterosexual relationships attending Comprehensive Care Centre at Mbagathi hospital.

The study used both descriptive and inferential statistics to determine both the adherence levels to oral PrEP and determinants of adherence to oral PrEP among the enrolled HIV seronegative partners in HIV discordant heterosexual relationships at Mbagathi Hospital CCC. The total respondents interviewed were 51.

4.2 Demographic factors

Most of the respondents were females represented by 52.9% (n=27) and males at 47.1% (n=24). A larger proportion of the respondents attained primary level of education (39.2%) (n=20), followed by those with secondary level of education (31.4%) (n=16), college (23.5%) (n=12) and few with University level of education (5.9%) (n=3).

The study participants who were self-employed represented a bigger proportion (56.9%) (n=29), followed by the unemployed (23.5%) (n=12) and employed (19.6%) (n=10).

Most of the respondents (38%) (n=19) of the respondents were within the age bracket of 30-39 years, followed by age bracket of 40-49 years (30%) (n=15), 20-29 years (24%) (n=12), 50-59 years (6%) (n=3) and over 60 years (2%) (n=1).

Table 1: Respondents demographic factors

Respondents demographic factors		Frequency	Percentage
Gender	Male	24	47.1
	Female	27	52.9
	Total	**51**	**100.0**
Age	20-29	12	24.0
	30-39	19	38.0
	40-49	15	30.0
	50-59	3	6.0
	>60	1	2.0
	Total	**50**	**100.0**
Education level	Primary	20	39.2
	Secondary	16	31.4
	College	12	23.5
	University	3	5.9
	Total	**51**	**100.0**
Employment status	Employed	10	19.6
	Self employed	29	56.9
	None	12	23.5
	Total	**51**	**100.0**

Effect of demographic factors on adherence to PrEP pills intake

A Binary logistic regression was performed to ascertain the effects of age, gender, level of education and employment status on the likelihood that participants adhered to PrEP medication. The regression model was statistically significant, χ^2 (8) = 27.647, p = 0.01.

The model explained 46.1% (Nagelkerke $R^2 = 0.461$) of the variance in adherence to PrEP medication and correctly classified 74.0% (n=37) of cases. Males were 1.009 times more likely to

adhere to intake of PrEP pills than females. Increase in age and education level was associated with an increased likelihood of overall adherence to PrEP. Employment status did not significantly influence adherence.

Table 2: Demographics coefficient table

Variables in the Equation									
		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	Gender(1)	.009	.760	4.990	1	.000	1.009	.228	4.476
	Age	.001	.039	2.989	1	.000	.999	.926	1.079
	Education level	.096	.372	5.796	1	.007	1.101	.531	2.281
	Job cadre	.196	.554	.126	1	.072	.822	.277	2.433
	Constant	1.176	2.430	.234	1	.628	3.243		
a. Variable(s) entered on step 1: Gender, Age, Education level, Job cadre.									

4.2.1 Parity factors observed among the respondents

The mean number of children was 2, the most common number of children per family was 1 and the variation in the number of children per family was 1.454. The minimum number of children was 1 and the maximum number of children was 7.

Desire to have more children did not influence PrEP adherence.

Table 3: Respondents number of children

Respondents statistics on number of children	
N	43
Mean	2.49
Mode	1
Std. Deviation	1.454
Minimum	1
Maximum	7

4.3 Adherence levels to oral PrEP

The adherence levels addressed in this study focused on three parameters which included; adherence to taking PrEP pills, adherence to time of taking PrEP pills and adherence of attending clinic appointments on scheduled dates. Adherence levels were assessed using respondents self-reports to responses given on several sub topics demonstrated below and respondents' clinic files validated some of that information by use of a checklist.

4.4 Respondents' adherence to intake of PrEP pills

Several parameters were assessed to determine respondents' adherence to intake of the PrEP pills as illustrated below.

4.4.1 Number of the respondents who were taking PrEP pill everyday

Majority of the respondents (89.4%) (n=42) reported that they were taking their pills of PrEP every day and had never missed a single dose while a small group of those who occasionally missed their PrEP pills was recorded (10.6%) (n=5).

Table 4: Respondents taking PrEP pill every day without fail

Type of response	Frequency	Percentage
Yes	42	89.4
No	5	10.6
Total	**47**	**100.0**

4.4.2 Number of the respondents who forgot to take PrEP pill occasionally

Most of the respondents (74%) (n=37) did not occasionally forget to take their PrEP while 26% (n=13) of the respondents occasionally forgot to take their pills.

Table 5: Respondents who forgot to take PrEP

Types of response	Frequency	Percentage
Yes	13	26.0
No	37	74.0
Total	**50**	**100.0**

4.4.3 Number of PrEP pills missed per month as reported by the respondents

Out of the respondents who reported to have missed taking their PrEP pills occasionally, 80% (n=8) missed between 1 to 2 pills per month while 20% (n=2) missed more than 4 pills in a month.

Table 6: Pills missed per month by respondents

Number of missed pills per month	Frequency	Percentage
1-2 pills	8	80.0
>4pills	2	20.0
Total	**10**	**100.0**

4.4.4 Action taken by the respondents when they missed taking PrEP pills

After missing to take their pills most of the respondents (72.7%) (n=8) chose to take their pills the following day, 18.2% (n=2) reported to abstain from sex with their partners and 9.1% (n=1) reported they take the pill during the next dose.

Table 7: Action taken by respondents when they missed to take PrEP pills

Types of responses	Frequency	Percentage
Took pill the following day	8	72.7
Waits for the next dosage	1	9.1
Abstinence from sex	2	18.2
Total	11	100.0

4.4.5 Checklist analysis on adherence assessment status from the respondents files

Adherence assessment status was documented in majority of respondents' files at 89.6% (n=43) while 10.4% (n=5) were not evaluated.

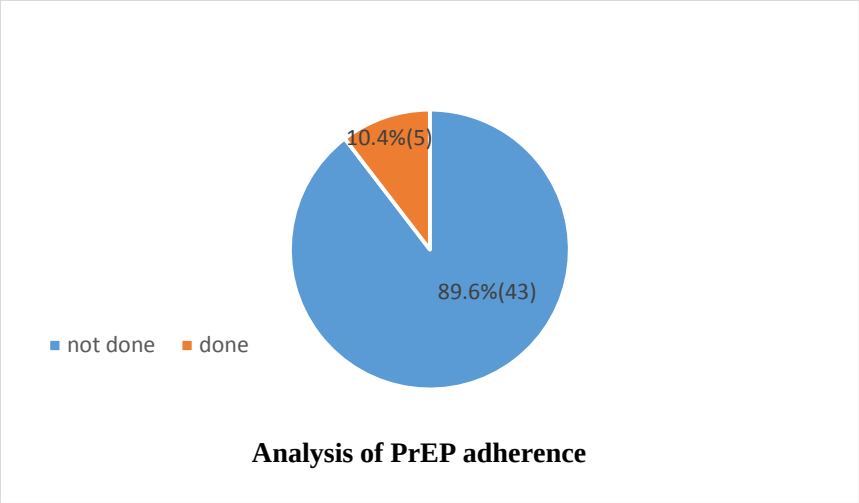

Figure 3: Analysis of PrEP adherence from respondents' medical files

4.4.6 Respondents' duration in years of being in HIV discordant relationship

The mean length of time of being in a serodiscordant heterosexual relationship was 4 years, the mode was 2 years and the standard deviation was 4.05733. The maximum number of years was 14 years. All the respondents were HIV negative and all of them (100%) have ever taken prep medication.

Table 8: Respondents statistics of duration in years of being in serodiscordant relationship

Summary of respondents statistics	
N	51
Mean	4.1157
Mode	2.00
Std. Deviation	4.05733
Minimum	0.00
Maximum	14.00

Effect of duration in years of being in HIV discordant relationship on adherence to PrEP pills intake

A Binary logistic regression was performed to ascertain the effects of duration in serodiscordant relationship and partner's HIV status on the likelihood that participants adhered to intake of PrEP pills. The regression model was statistically significant, χ^2 (7) = 15.248, p = 0.04

The model explained 25.4% (Nagelkerke $R^2 = 0.254$) of the variance in adherence to PrEP pills and correctly classified 79.2% (n=34) of cases. Increase of the years of being in a serodiscordant relationship was associated with an increased likelihood to adhere to intake of PrEP pills.

Table 9: coefficient table on duration of serodiscordant relationship, desire for more children and viral load status

Variables in the Equation									
		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	Period in serodiscordant relationship	.042	.096	7.187	1	.046	1.042	.863	1.259
	HIV Pos partner's viral load status (2)	22.551	231.536	10.689	1	.000	76.048	0.000	
	Need for more children	3.097	2.497	1.538	1	.215	22.140	.166	2958.107
	Constant	-43.987	46211.072	.000	1	.999	.000		
a. Variable(s) entered on step 1: Period in serodiscordant relationship, Partner's HIV status, Need for more children									

4.4.7 Reasons that respondents gave for agreeing to be initiated on PrEP pills

Most of the respondents reported that they started taking PrEP because they wanted to get prevention from HIV infection (49%) (n=25) followed by those who wanted to conceive (23.5%) (n=12). Other respondents started PrEP because of media sensitization, some wanted to have sex with their partners without using condoms and others were advised from the clinic on the importance of using PrEP among other reasons like during pregnancy.

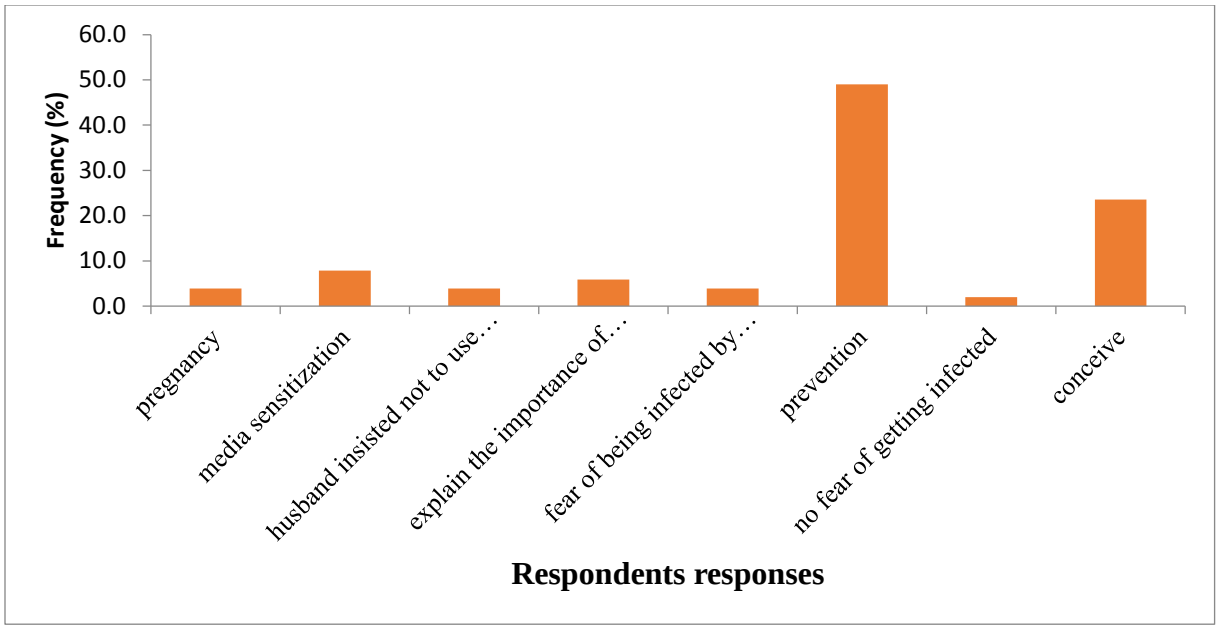

Figure 4: Respondents responses on agreeing to PrEP initiation

4.4.8 Number of respondents who used condoms during sex when taking PrEP pills

Most of the respondents (53%) (n=27) when taking PrEP were not using condoms when engaging in sexual intercourse with their partners while 47% (n=24) were using condoms.

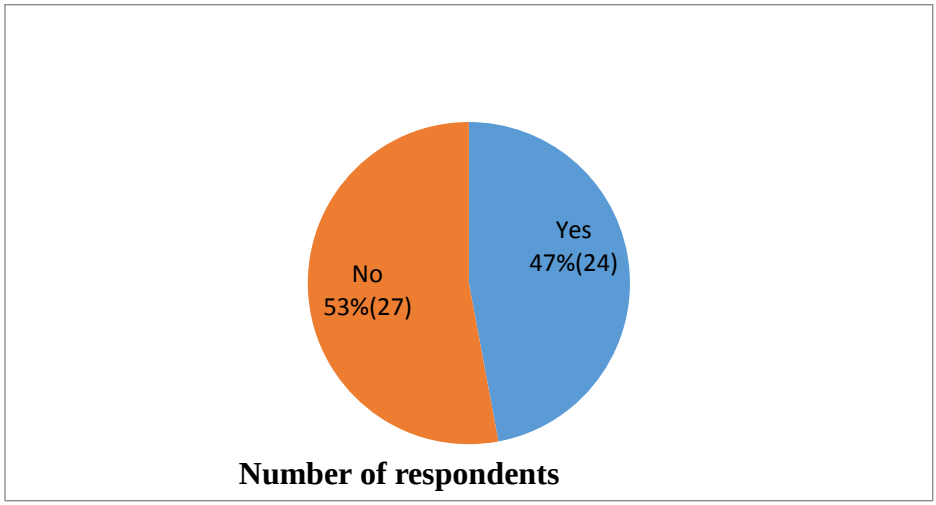

Figure 5: Respondents that used condom when taking PrEP

4.4.8.1 Checklist analysis of respondents condom use as documented in their files.

Most of the individuals (39%) (n=18) used condoms but not in a consistent basis while 28% (n=13) did not make use of condoms at all. 24% (n=11) used condoms consistently while 8.7% (n=4) were issued with condoms and used them for 3 months only.

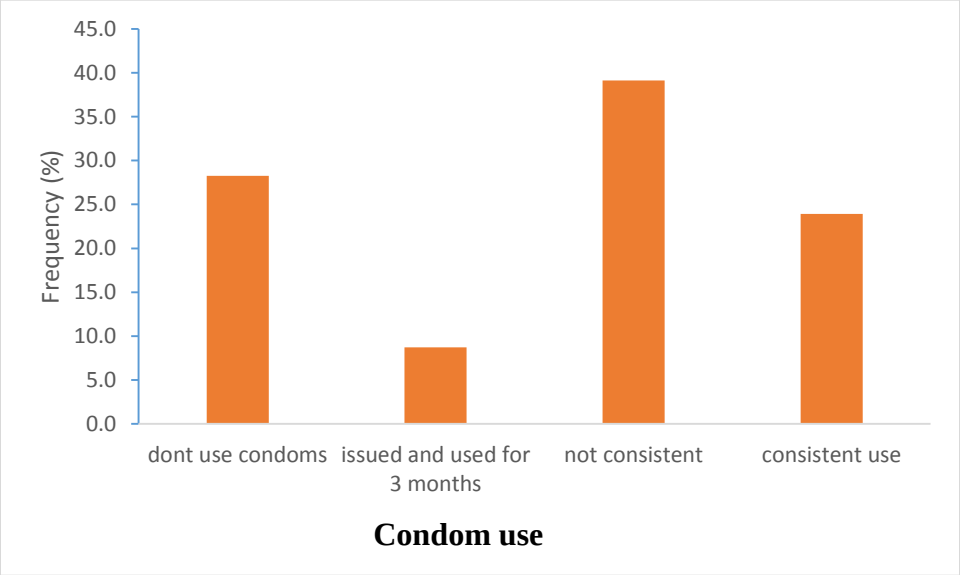

Figure 6: Respondents condom use as documented in their files

4.4.9 Number of respondents who used other family planning methods apart from condoms

Majority of the respondents (80.0%) (n=20) were not using other family planning methods other than condoms.

Table 10: Respondents use of other family planning methods besides condom

Respondents responses	Frequency	Percentage
Yes	5	20.0
No	20	80.0
Total	**25**	**100.0**

4.4.10 Respondents' duration of sex abstinence after PrEP pills initiation.

Majority of the respondents 95.9% (n=47) took more than 7 days after initiation of the PrEP drugs before engaging in sex without condom while 4.1% (n=2) did not wait for the 7 days to elapse before engaging in unprotected sex as recommended by the guidelines.

Table 11: Respondents duration of taking PrEP drugs before engaging in sex without condom

Number of days	Frequency	Percentage
<7	2	4.1
>7	47	95.9
Total	**49**	**100.0**

4.4.11 Number of respondents who used other HIV prevention methods when unable to take PrEP pills

Most of the respondents (64.3%) (n=9) reported that they used other HIV prevention methods when unable to use PrEP pills consistently while 35.7% (n=5) didn't use any other HIV prevention method when unable to use PrEP pills consistently.

Table 12: Respondents use of other HIV prevention methods when taking PrEP

Type of responses	Frequency	Percentage
Yes	9	64.3
No	5	35.7
Total	**14**	**100.0**

4.4.12 Types of support that respondents got during intake of PrEP pills

This assessed the support respondents received in enhancing them to take PrEP pills effectively either from their sex partner, relatives, friends and health care providers.

4.4.12.1 Number of the respondents who involved their partner in decision making on use of PrEP pills

Majority of the respondents (90.2%) (n=46) who took PrEP drugs involved their partners in making decision of using PrEP while 9.8% (n=5) didn't involve their partner.

Table 13: Respondents involvement of partner in decision making on use of PrEP pills

Types of responses	Frequency	Percentage
Yes	46	90.2
No	5	9.8
Total	51	100.0

4.4.12.2 Number of respondents that disclosed to other people apart from their partner on use of PrEP pills

Majority of the respondents who took PrEP drugs did not disclose to others about taking PrEP apart from their partners, accounting for 88.2% (n=45).

Table 14: Respondents disclosure to other people apart from partner on use of PrEP pills

Types of responses	Frequency	Percentage
Yes	6	11.8
No	45	88.2
Total	51	100.0

4.4.12.3 Kind of reaction that the respondents received from other people whom they disclosed to on use of oral PrEP pills other than their partner

The respondents revealed that after disclosure of taking PrEP to other people other than their partners, some people were very supportive and encouraged them while others were shocked that they were taking PrEP all at equal proportions of 33.3% (n=2).

Table 15: Reaction of people after respondents disclosed use of PrEP pills to them

Description of reaction	Frequency	Percentage
very supportive	2	33.3
encouragement	2	33.3
shocked	2	33.3
Total	6	100.0

4.4.12.4 Plan for remembering to take PrEP pill everyday as stated by the respondents

Most of the respondents 58% (n=29) used alarms as a reminder to take PrEP, 26% (n=13) reported that they had registered in their mind. There were those who were reminded by watching 9pm television news, motivation from fear of being infected and positive impact of HIV prevention.

Table 16: Respondents plan for remembering to take PrEP pill every day

Methods used to remember	Frequency	Percentage
Positive impact of HIV prevention	1	2.0
Alarm	29	58.0
Fear of being infected by HIV	1	2.0
Registered in mind	13	26.0
Noting down	2	4.0
Watching news	4	8.0
Total	50	100.0

4.4.12.5 Motivating factors and barriers to consistent pill use as stated by the respondents

Protection from contracting HIV was reported as the motivating factor to most of the respondents at 50% (n=27) with side effects of PrEP drugs as the leading barrier to consistent pill use at 5.6% (n=3).

Table 17: Respondents motivating factors and barriers to consistent pill use

Description of responses	Frequency	Percentage
Breastfeeding child	1	1.9
Barrier sides effects of nausea	3	5.6
Motivating factors	9	16.7
Protection from HIV	27	50.0
Need to conceive	9	16.7
Sex satisfaction	1	1.9
Assured of safety	2	3.7
Registered in mind	1	1.9
Lack of time to attend clinic	1	1.9
Total	**54**	**100.0**

4.4.12.6 Barriers encountered by the respondents that hindered their good adherence to PrEP pills

Those taking PrEP medication experienced barriers that hindered good adherence. Some of the mentioned barriers included long distance relationships (28.6%) (n=2) and lack of knowledge on consistency of taking drugs (28.6%) (n=2).

Table 18: Barriers encountered by respondents that hindered their good adherence to PrEP drugs

Types of responses	Frequency	Percentage
Long distance relationship	2	28.6
Lack of knowledge on consistency of taking drugs	2	28.6
Work involves a lot of travelling	1	14.3
side effects	1	14.3
Irregular periods	1	14.3
Total	**7**	**100.0**

4.4.12.7 Measures taken by the respondents to address stated barriers of adherence to PrEP pills

Following what the clinician recommends was stated by most of the respondents (33.3%) (n=2) as a measure to address stated barriers to adherence to PrEP, visiting the clinic before travelling to refill PrEP (16.7%) (n=1), maintaining clinic appointments (16.7%) (n=1), consistent time of taking PrEP drugs (16.7%) (n=1) and taking a break from PrEP (16.7%) (n=1).

Table 19: Respondents measures to address stated barriers to adherence

Description of measures taken	Frequency	Percentage
Consistent time of taking drugs	1	16.7
Visiting the clinic before travelling to refill PrEP	1	16.7
Follow what clinician says	2	33.3
Maintaining clinic appointments	1	16.7
Taking a break from PrEP	1	16.7
Total	**6**	**100.0**

4.4.12.8 Number of the respondents receiving partners support on adherence to PrEP drugs

Majority of the respondents (80%) (n=41) received adherence support from their partners.

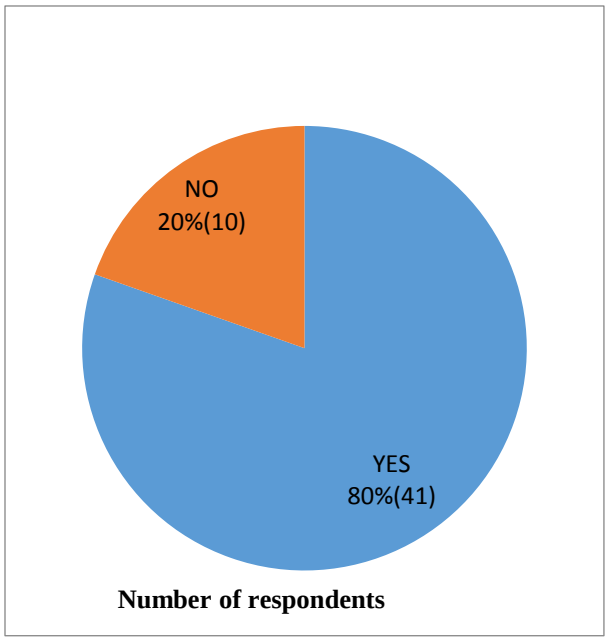

Figure 7: Respondents receiving adherence support from partner

Effect of receiving support when taking PrEP pills on adherence to intake of PrEP medication

Some of the factors that involved support in taking PrEP pills and were found to influence respondents' adherence to PrEP pills intake included the following; Use of condom together with PrEP pills was found to decrease respondents' adherence to intake of PrEP pills and the respondents who involved their partner in making decision on using PrEP medication were also found to have lower levels of adherence to intake of PrEP pills.

The respondents that engaged their partners in adherence support and had a plan of remembering to take their PrEP pill were found to have good adherence to intake of PrEP pills.

Table 20: Support of PrEP pills intake on adherence.

Description of the intervention		Adherence to PrEP medication		N
		Yes	No	
Using condom when engaging in sexual intercourse with partner whilst taking PrEP	Yes	5(21.7%)	18(78.3%)	23
	No	8(29.6%)	19(70.4%)	27
Involving partner in making decision on using PrEP medication	Yes	13(28.3%)	33(71.7%)	46
	No	0(0%)	4(100%)	4
Engaging partner on adherence support	Yes	30(73.2%)	11(26.8%)	41
	No	7(77.8%)	2(22.2%)	9
Ways of remembering to take PrEP pill	Positive impact of HIV prevention	1(100%)	0(0%)	1
	Alarm	18(66.7%)	9(33.3%)	27
	fear of being infected by HIV	1(100%)	0(0%)	1
	Registered in mind	12(92.3%)	1(7.7%)	13
	Noting down	2(100%)	0(0%)	2
	Watching 9pm news	3(75%)	1(25%)	4

4.4.13 Respondents' behavioral change factors that affected adherence to PrEP pills intake

4.4.13.1 Number of respondents that took a break from taking PrEP pills

Majority of the respondents (80.4%) (n=41) did not take breaks from taking PrEP medication while some respondents (19.6%) (n=10) reported to have taken PrEP breaks.

Table 21: Respondents break from taking PrEP medication

Types of response	Frequency	Percentage
No	41	80.4
Yes	10	19.6
Total	**51**	**100.0**

4.4.13.2 Number of respondents that engaged in protected sex (used condoms) after taking a break from use of PrEP pills

Most of the respondents (72%) (n=36) engaged in protected sex after they stopped taking PrEP medication.

Table 22: Respondents that engaged in protected sex (used condoms) after they stopped taking PrEP

Types of responses	Frequency	Percentage
No	14	28.0
Yes	36	72.0
Total	50	100.0

4.4.13.3 Respondents' frequency of doing a HIV test

Majority of the respondents (96%) (n=48) had a HIV test done after every 3 months.

Table 23: Respondents' frequency of doing a HIV test

Frequency of HIV test	Frequency	Percentage
After 3 months	48	96.0
Once a year	1	2.0
2 times since 2016	1	2.0
Total	50	100.0

4.4.13.4 Respondents' adherence to routine HIV test every 3 months as recommended by the clinician.

Most of the participants (69.2%) (n=9) on PrEP medication adhered to a routine HIV test every 3 months.

Table 24: Adherence to routine HIV testing every 3 months as recommended by clinician

Types of responses	Frequency	Percentage
Yes	9	69.2
No	4	30.8
Total	**13**	**100.0**

Effect of behavioral factors on adherence to intake of PrEP pills

A Binary logistic regression was performed to ascertain the effects of taking a break from taking PrEP drugs, engaging in protected sex (used condoms) after taking a break from use of PrEP and frequency of doing a HIV test on the likelihood that participants adhered to intake of PrEP pills. The regression model was statistically significant, χ^2 (7) = 22.551, p = 0.04.

The model explained 31.5% (Nagelkerke $R^2 = 0.315$) of the variance in adherence to intake of PrEP medication and correctly classified 75.0% (n=7) of cases. Engaging in protected sex (used condoms) after taking a break from use of PrEP and increased frequency of doing a HIV test significantly increased adherence to intake of PrEP pills.

Table 25: Behavioral factors coefficient table

Variables in the Equation									
		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	Taking a break from taking PrEP drugs (1)	20.287	40192.970	1.000	1	.000	5.970	0.000	
	Engaged in protected sex (used condoms) after taking a break from use of PrEP	-1.609	1.483	1.177	1	.028	.200	.011	3.661
	Frequency of doing a HIV test	20.287	40192.961	8.184	1	.000	0.926	0.000	
	Constant	-17.761	40192.961	.000	1	1.000	.000		
a. Variable(s) entered on step 1: Taking a break from taking PrEP drugs, Engaged in protected sex (used condoms) after taking a break from use of PrEP, Frequency of doing a HIV test.									

4.4.14 Number of respondents that reported side effects after intake of PrEP pills

A bigger proportion of the respondents (58.3%) (n=30) experienced side effects after using PrEP medication for the first 3 months.

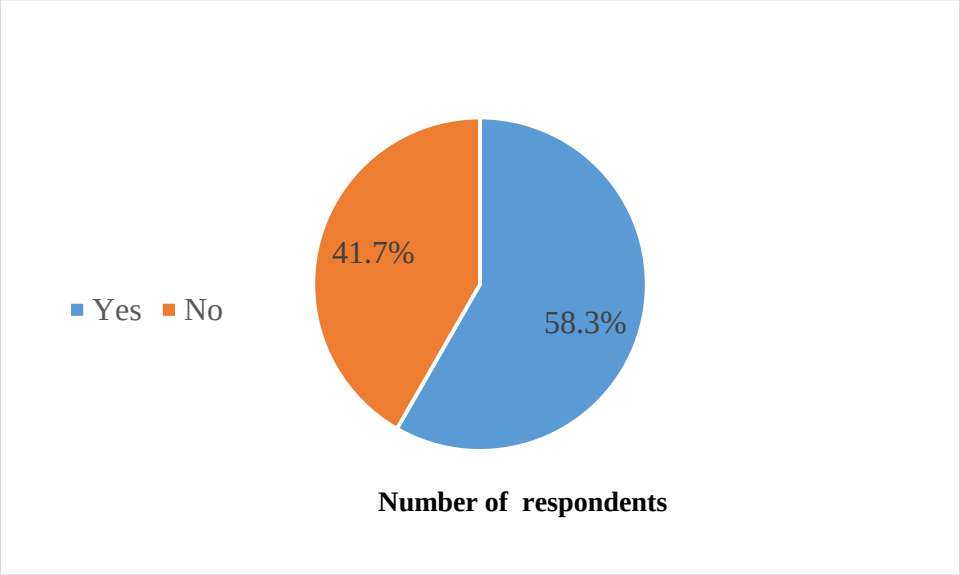

Figure 8: Number of respondents who experienced side effects after intake of PrEP

4.4.14.1 Classification of the side effects reported by the respondents.

Some of the respondents (30.8%) (n=16) taking PrEP medication experienced headaches, followed by nausea (17.3%) (n=9), dizziness (9.6%) (n=5) among many other side effects that were reported.

Table 26: Side effects reported after PrEP pills intake

Description of side effects	Frequency	Percent
Nausea	9	17.3
Headache	16	30.8
Loss of appetite	2	3.8
Vomiting	4	7.7
Diarrhea	4	7.7
Abdominal fullness	3	5.8
Loose motion	2	3.8
Dizziness	5	9.6
Constipation	1	1.9
Foul smell	1	1.9
Sneezing	1	1.9
Nose bleeding	1	1.9
Joint pains	1	1.9
General malaise	1	1.9
Dry skin	1	1.9
Total	52	99.8

4.4.14.2 Action taken by respondents after experiencing side effects from PrEP pills intake

Most of the respondents (60%) (n=3) continued taking PrEP despite experiencing the side effects. 40% (n=2) stopped taking the PrEP after experiencing the side effects.

Table 27: Respondents action after experiencing side effects from PrEP pills intake

Type of responses	Frequency	Percentage
Continued taking the pills	3	60.0
Stopped using the pills	2	40.0
Total	**5**	**100.0**

Effect of PrEP pills side effects on adherence to intake of PrEP pills

A Binary logistic regression was performed to ascertain the effects of side effects on the likelihood that participants adhered to PrEP medication. The regression model was statistically significant, χ^2 (1) = 21.910, p =0.003

The model explained 55.0% (Nagelkerke $R^2 = 0.550$) of the variance in adherence to PrEP medication and correctly classified 88.1% (n=30) of cases. Encountering side effects significantly reduced adherence to intake of PrEP pills.

Increase in chance of encountering a side effect was associated with a reduction in adherence to PrEP medication.

Table 28: Side effects experienced coefficient table

Variables in the Equation									
		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	Encountering side effects	-1.543	1.116	21.910	1	.003	4.678	.525	41.710
	Constant	-17.204	18080.733	.000	1	.999	.000		
a. Variable(s) entered on step 1: Encountering side effects									

4.4.14.3 Ways of improving effects of side effects on adherence to PrEP pills intake as reported by the respondents

Some of the respondents (28.6%) (n=2) had the opinion that getting a better explanation on the side effects from the medical personnel would make them continue taking the PrEP as recommended.

Table 29: Ways of improving effects of side effects on adherence

Description of responses	Frequency	Percentage
Comfortable with the drugs	1	14.3
Reduce pill burden in comorbid conditions	1	14.3
Eating sugar, lemon/orange	1	14.3
Following up appointments	1	14.3
Get a better explanation	2	28.6
Report to the clinician	1	14.3
Total	**7**	**100.0**

4.4.14.4 Number of respondents willing to continue with intake of PrEP pills

If unable to take the PrEP medication regularly, Majority of the respondents (88.9%) (n=8) would still continue taking PrEP pills while 11% (n=1) would stop taking PrEP pills.

Table 30: Respondents' desire for continuing with PrEP medication

Types of responses	Frequency	Percentage
Yes	8	88.9
No	1	11.1
Total	**9**	**20.0**

4.4.15 Attitude of respondents towards intake of oral PrEP pills

4.4.15.1 Respondents' understanding on oral PrEP pills use

Majority (98.0%) (n=50) of the respondents stated that oral PrEP was used as a modality of prevention of HIV infection to the negative partner by the infected partner and 2% (n=1) of respondents indicated it is used by serodiscordant couples to conceive when one partner is HIV positive to prevent HIV infection.

Table 31: Respondents understanding of PrEP pills use

Description of understanding	Frequency	Percentage
Prevent one from getting infected by partner	50	98.0
Conceiving when one partner is positive	1	2.0
Total	**51**	**100.0**

4.4.15.2 Importance of taking PrEP as stated by the respondents

Most of the respondents (73.1%) (n=38) stated that using PrEP had benefited them by being safe from acquiring and getting HIV infection, 9.6% (n=5) stated PrEP had helped them to enjoy unprotected sex with their HIV infected partner, 7.7% (n=4) stated PrEP had helped them to conceive and remained HIV negative, 7.7% (n=4) stated it had helped them to sustain their marriage and 1.9% (n=1) stated they had improved confidence of remaining protected from getting HIV infected.

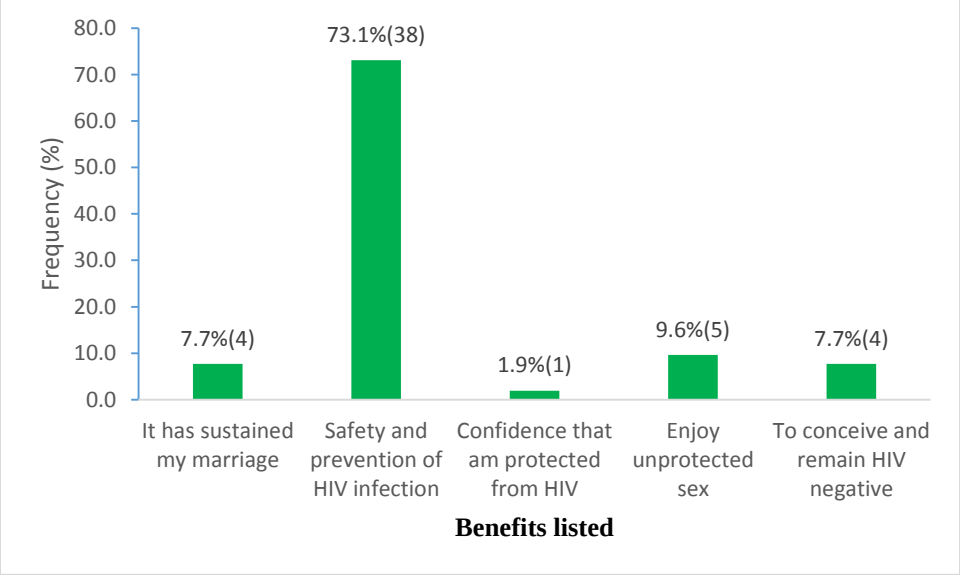

Figure 9: Benefits of PrEP as stated by the respondents

Effect of attitude on adherence to intake of PrEP pills

Attitude factors were assessed to determine their association with adherence to PrEP pills. Most of the respondents (73.5%) (n=36) who showed they had knowledge on PrEP and those who demonstrated confidence in PrEP safety and prevention from HIV infection (70.3%) (n=26) were found to have good adherence to intake of PrEP pills.

Table 32: Summary of attitude responses towards PrEP use

Description of attitude factors		Adherence to PrEP medication		N
		Yes	No	
Knowledge on PrEP	Prevent one from getting infected by partner	36(73.5%)	13(26.5%)	49
	Conceiving when one partner is positive	1(100%)	0(0%)	1
	It has sustained my marriage	4(100%)	0(0%)	4
Taking of PrEP helping	Safety and prevention of HIV infection	26(70.3%)	11(29.7%)	37
	Confidence that am protected from HIV	1(100%)	0(0%)	1
	Enjoy unprotected sex	3(60%)	2(40%)	5
	To conceive and remain HIV negative	3(100%)	0(0%)	3
Challenges encountered when refilling PrEP	long waiting time	0(0%)	1(100%)	5
	lack of transport to clinic	0(0%)	1(100%)	4
	side effects	0(0%)	1(100%)	1
	work issues	0(0%)	1(100%)	1
	anxiety	0(0%)	1(100%)	1
	lack of time	1(50%)	1(50%)	2

4.4.16 Respondents' social factors associated with PrEP use

4.4.16.1 Number of respondents who had a sexual partner outside their marital partner

Majority of the respondents did not have any sexual partner outside their marital partners (88.2%) (n=45) while 11.8% (n=6) had sexual partners outside their marital partners. The number of sexual partners outside marital partners stated was 1. All individuals who had extra marital affairs stated that they knew the HIV status of their sex partners.

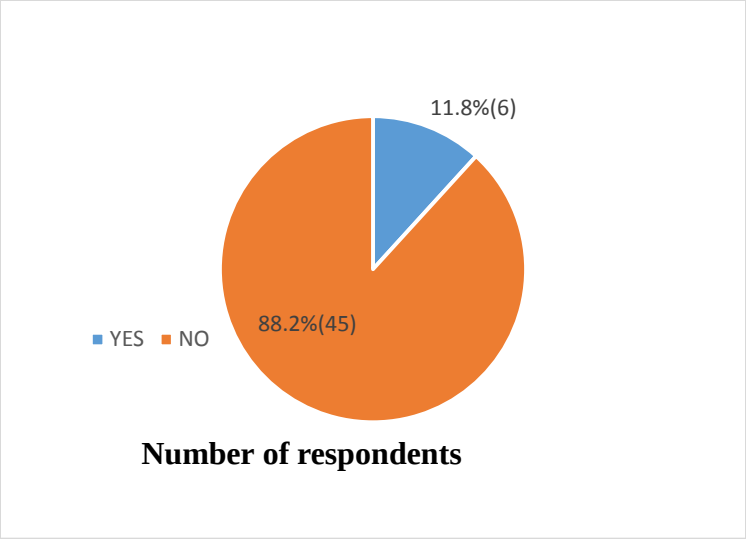

Figure 10: Respondents with sexual partner outside their marital partner

4.4.16.2 Number of respondents that used condoms when engaging in extra marital sex

Most of the respondents (66.7 %) (n=4) used condoms when engaging in sex with other sexual partners other than their marital partner.

Table 33: Respondents' use of condoms when engaging in extra marital affairs

Type of responses	Frequency	Percentage
Yes	4	66.7
No	1	16.7
use condoms sometimes	1	16.7
Total	6	100.0

4.4.16.3 Respondents' frequency of having sex with their partner in a month

Most of the respondents engaged in sex 6-10 times in a month at 41.2% (n=21), 1-5 times in a month at 37.3% (n=19), 11-15 times at 17.6% (n=9) and more than 15 times at 3.9% (n=2).

Table 34: Respondents' frequency of having sex with their partner in a month

Number of times per month	Frequency	Percentage
1-5	19	37.3
6-10	21	41.2
11-15	9	17.6
>15	2	3.9
Total	**51**	**100.0**

4.4.16.4 Number of respondents that used alcohol and other substances of abuse

A small group of the respondents at 19.6% (n=10) took alcohol or any other substance that affects mental judgement while 78.4% (n=40) reported that they did not take alcohol or any other substance of abuse.

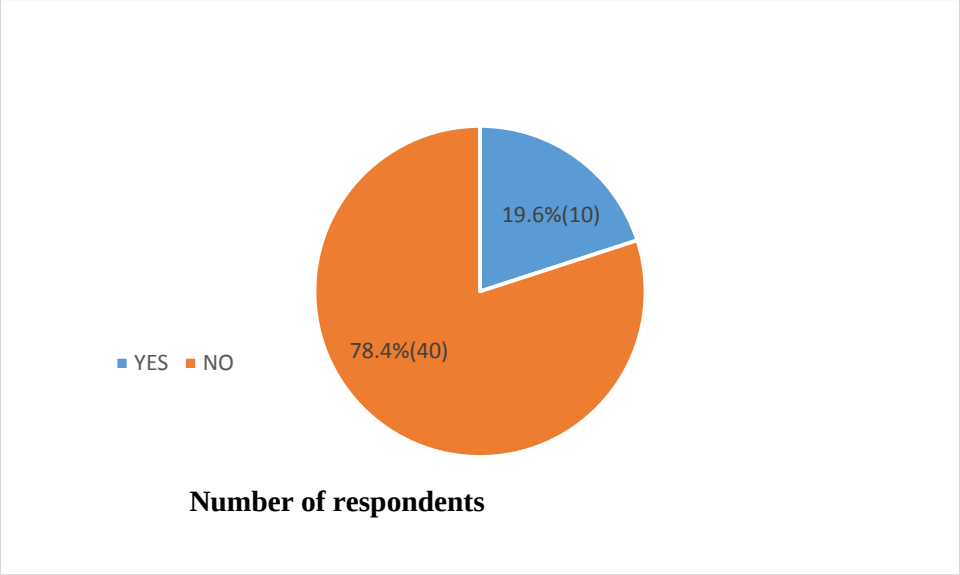

Figure 11: Number of respondents that took alcohol or any other substance

Of the 19.6% (n=10) of the individuals who took alcohol or any other substance that affects mental judgement, 90.9% (n=9) occasionally used alcohol while the remaining 9.1% (n=1) were cigarette smokers.

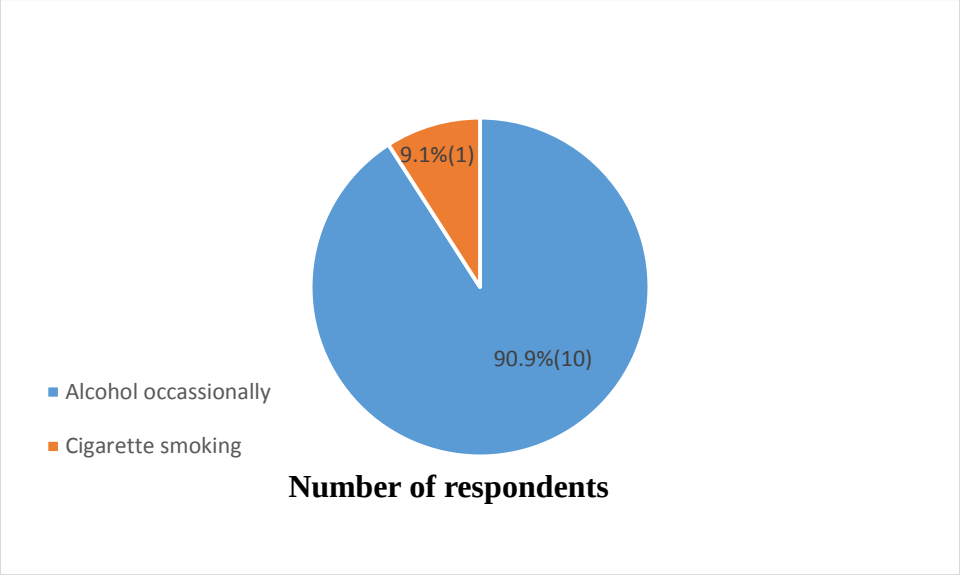

Figure 12: Number of respondents that used alcohol and smoked cigarette

4.4.16.5 Effects of interference with respondents memory in adherence to PrEP pills after use of alcohol or other substance of abuse

55.6% (n=5) of the respondents reported that they don't remember to take their PrEP when intoxicated with alcohol while 44.4% (n=4) remember to take their PrEP after use of alcohol.

Table 35: Number of respondents that remembered to take PrEP while intoxicated

Type of response	Frequency	Percentage
Yes	4	44.4
No	5	55.6
Total	**9**	**100.0**

Association between social factors and adherence to intake of PrEP pills

Chi-square analysis was done to determine the significance of the association between social factors and adherence to PrEP medication among serodiscordant couples. Having a sexual partner outside marital partner (p value = 0.04) and taking alcohol or other factors that impairs judgement (p value = 0.05) significantly reduced adherence to intake of PrEP pills.

Table 36: Respondents' social factors summary and Chi square summation

Description of social factors		Adherence to PrEP		N	χ2(P-value)
		Yes	No		
Having sexual factors outside marital partner	Yes	1(16.7%)	5(83.3%)	6	10.619 (0.0378)
	No	12(27.3%)	32(72.7%)	44	
Taking alcohol or other factors that impairs judgement	Yes	3(30%)	7(70%)	10	16.404 (0.0474)
	No	10(25%)	30(75%)	40	
Taking PrEP pill after taking judgement impairing substance	Yes	2(66.7%)	1(33.3%)	3	0.879(0.0134)
	No	1(16.7%)	5(83.3%)	6	

4.4.17 Checklist analysis of respondents' indication for PrEP prescription as documented in respondents' files

All the 51 respondents were in HIV discordant heterosexual relationship. PrEP was indicated for respondents whose partners were HIV positive (60%) (n=31), desire to conceive with HIV positive partner (30%) (n=15), partner refused to use condom (5%) (n=3).

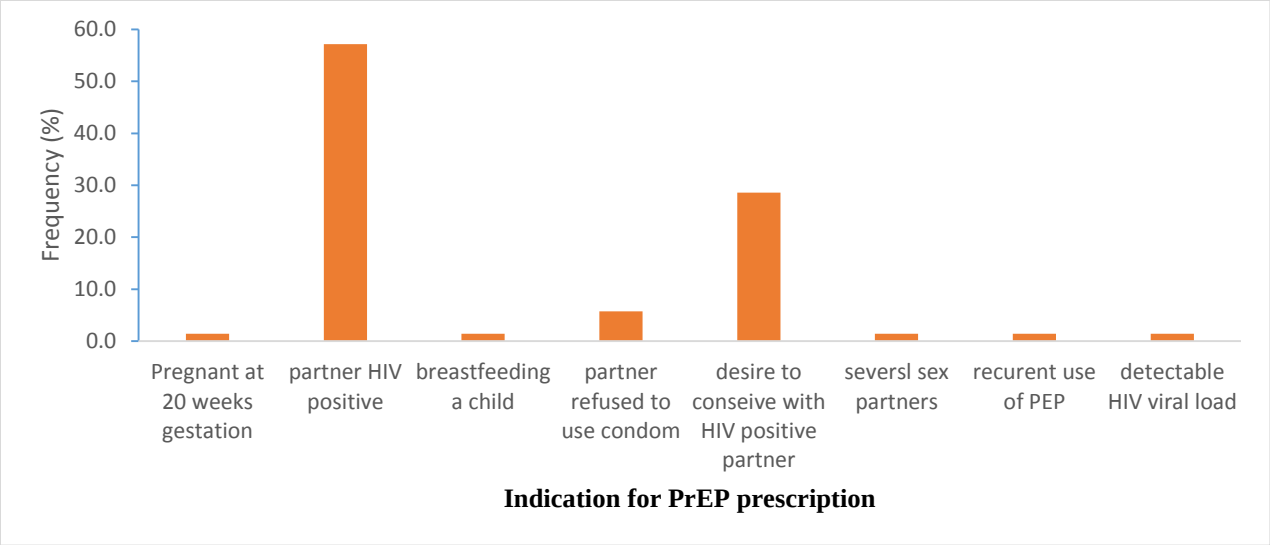

Figure 13: Checklist analysis of respondents' indication for PrEP prescription as documented in respondents' files

Persons whose partners had detectable HIV viral load were 76.048 times more likely to adhere to PrEP pills than those whose partners viral load were undetectable.

4.4.18 Checklist analysis of the regimen of PrEP pills prescribed as documented in the respondents' files

All the respondents were prescribed Tenofovir (TDF) 300mg and Emtricitabine (FTC) 200mg fixed dose combination which was either dispensed for 1 month or 3 months duration.

Table 37: Checklist analysis of the regimen of PrEP pills prescribed as documented in the respondents' files

PrEP medication prescribed and Duration	Frequency	Percentage
TDF/FTC OD*3/12	47	95.9
TDF/FTC OD*1/12	1	2.0
TDF/FTC OD*3/7	1	2.0
Total	**49**	**100.0**

4.4.19 Respondents' duration of taking PrEP pills in months

The mean period of taking PrEP in months was 11 months, mode was 24 months and a standard deviation of 7.651. The respondents' maximum period of taking PrEP was 24 months with a minimum period of 1 month.

Table 38: Respondents' duration of taking PrEP pills in months

Statistics for duration in months on oral PrEP	
N	51
Mean	11.14
Mode	24
Std. Deviation	7.651
Minimum	1
Maximum	24

4.5 Respondents' adherence to time of PrEP pills intake.

Most of the respondents (58%) (n=30) took prep at 9pm, 20% (n=10) took at 10pm and 12% (n=6) at 8pm. A few of the respondents took their pills in the morning hours. Majority (96%) (n=49) of them were consistent with their time of taking PrEP pills.

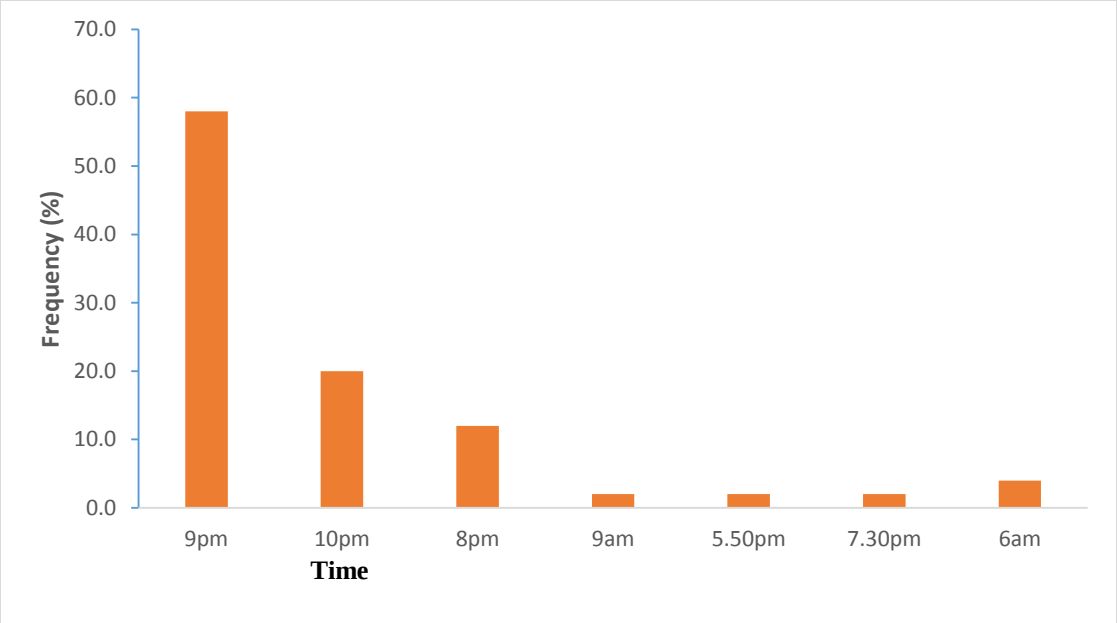

Figure 14: Respondents time of taking PrEP

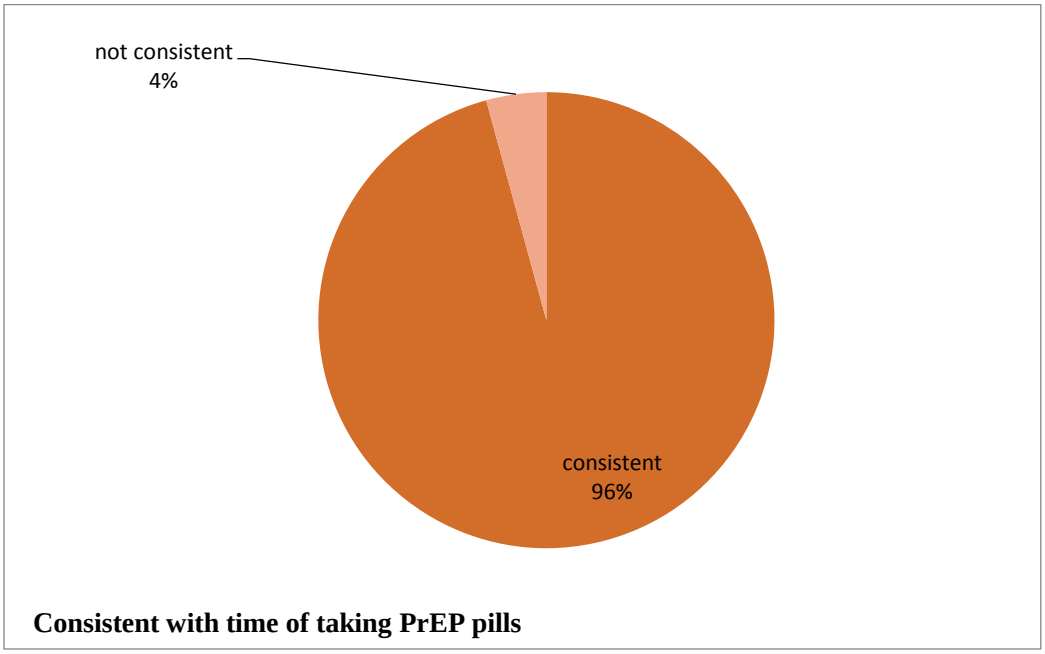

Figure 15: Adherence to time of taking PrEP

4.6 Respondents adherence to scheduled clinic appointments

Majority of the respondents (80%) (n=40) stated that they did not miss their clinic appointments while 20% (n=11) missed their appointments.

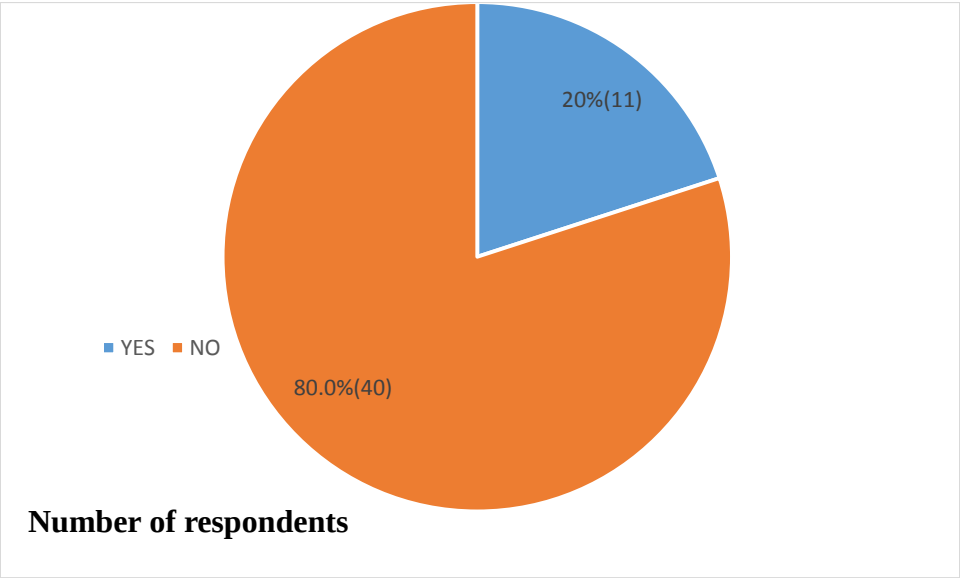

Figure 16: Number of respondents that missed clinic appointments

4.6.1 Checklist results from the respondents' files on adherence to clinic appointment

Out of the 11 respondents who missed their scheduled clinic appointments; 81.9% (n=9) of all the respondents had missed one appointment while the remaining 18.2% (n=2) had missed two appointments.

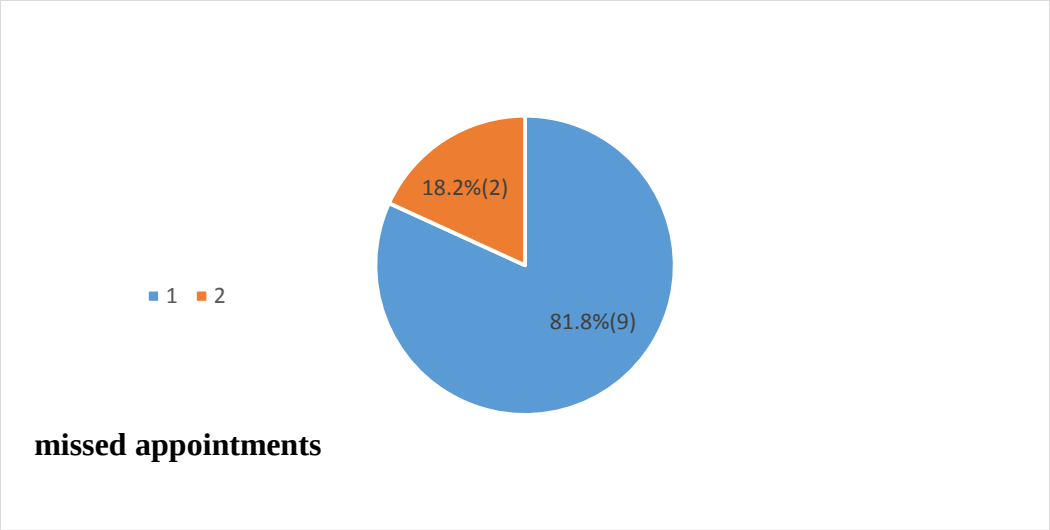

Figure 17: Number of missed appointments by respondents

Association between missing clinic appointments and adherence to intake of PrEP pills.

Missing clinic appointments was not found to significantly influence adherence to intake of PrEP pills (p value=0.65).

Table 39: Chi square of association between missing clinic appointments and adherence to intake of PrEP pills

Missing clinic appointments	Adherence to PrEP medication		N	χ2(P-value)
	Yes	No		
Yes	3(30.0%)	7(70.0%)	10	0.206 (0.650)
No	9(23.1%)	30(76.9%)	39	

4.6.2 Various methods of refilling PrEP drugs when far from the clinic as stated by the respondents.

Most of the respondents (69.7%) (n=23) stated they will get PrEP from the nearest government health facility when far from the clinic, 18.2% (n=6) stated that they will always ensure they had enough stock of drugs to prevent such a scenario from occurring.

Table 40: Respondents ways of refilling PrEP drugs when far from the clinic

Respondents description	Frequency	Percentage
Nearest government health facility	23	69.7
From the nearest clinic	3	9.1
Get enough stock of drugs	6	18.2
Inform me what to do	1	3.0
Total	**33**	**100.0**

4.6.3 Challenges faced by the respondents when refilling PrEP pills

Some of the respondents highlighted challenges experienced while refilling their PrEP drugs as lack of time to come to the clinic from their busy schedule and long waiting time at the clinic both accounting 25%, (n=8) lack of transport 15% (n=5), anxiety 15% (n=5) among other challenges.

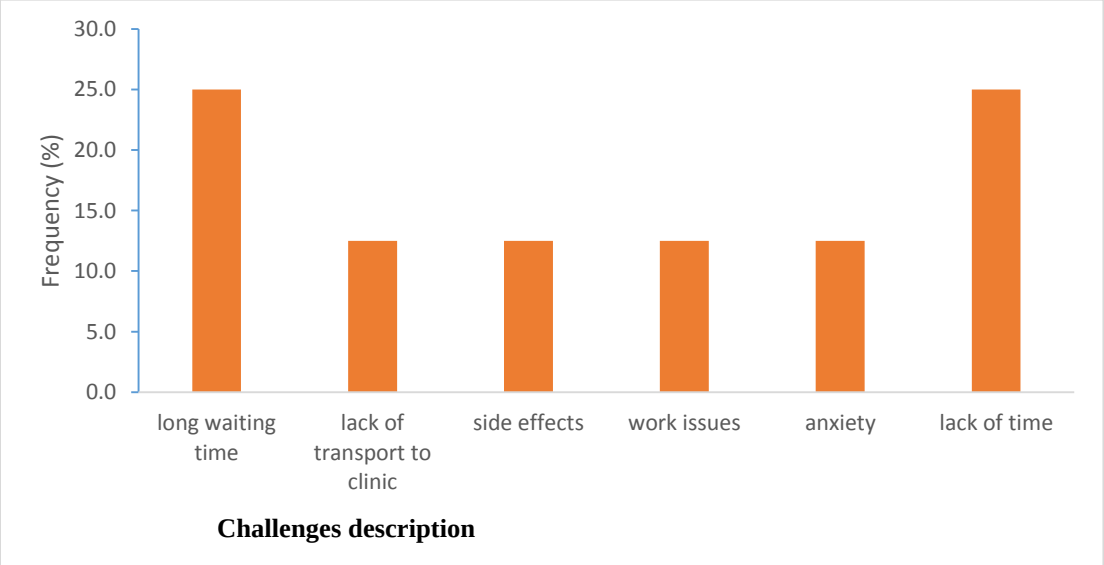

Figure 18: Challenges encountered by respondents when refilling PrEP

Those respondents who stated they encountered challenges when refilling PrEP were found to have less adherence to scheduled clinic appointments.

4.6.4 Checklist analysis of laboratory investigations done from the respondents files

The HIV status of all the 51 respondents remained negative, hence there was no seroconversion. The only baseline laboratory investigations done to only three respondents were liver function test (16.7 %) (n=1) and hepatitis B and C screening (33.3%) (n=3).

Table 41: Checklist analysis of laboratory investigations done from the respondents files

Baseline investigations done	Frequency	Percentage
ALT	1	16.7
Liver function test	1	16.7
Hepatitis B screening	2	33.3
Hepatitis C screening	2	33.3
Total	**6**	**100.0**

4.6.5 Checklist analysis of respondents' clinic data from their files

The checklist obtained secondary data from all the respondents' clinic files to assess clinicians/medical personnel inputs on PrEP outcome and auditing the documentation of the clinics' medical records.

4.6.5.1 Analysis of counselling status for respondents who defaulted clinic appointments

85.7% (n=6) of the respondents' files who had a missing appointment had a defaulter counselling status completed while in 14.3% (n=1) of respondents' files, were not completed.

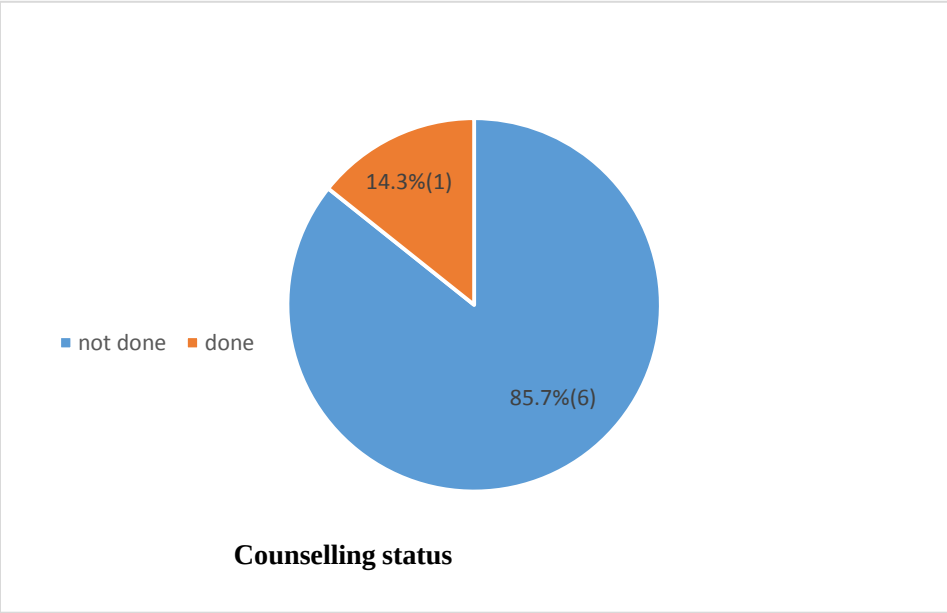

Figure 19: Analysis of counselling status of respondents who missed clinic

4.6.5.2 Respondents' screening status of sexually transmitted infections (STI) in every clinic visit

Majority of the respondents' files (96.1%) (n=49) had STI screening status completed while 3.9% (n=2) were not completed.

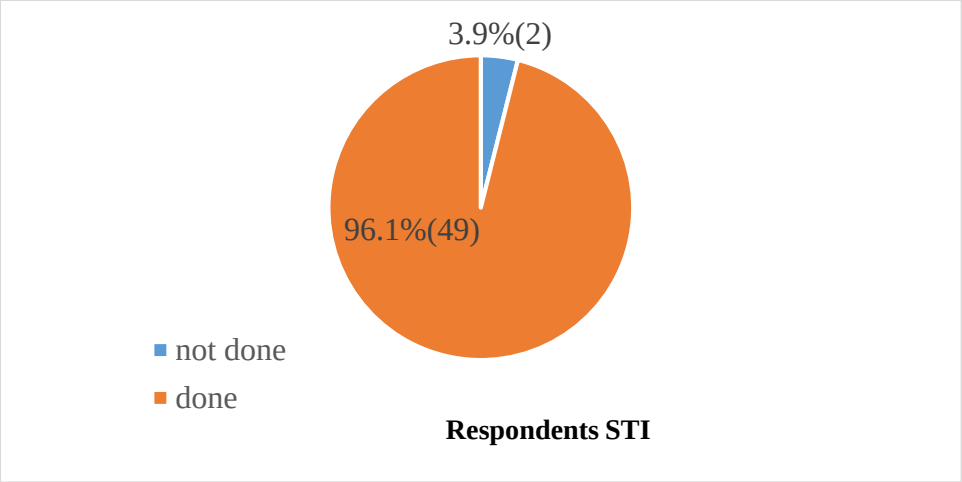

Figure 20: Analysis of respondents STI screening status

4.6.5.3 Number of respondents' HIV tests done in 12 months

All the respondents had their HIV tests done regularly after every three months with the month of February recording highest number of HIV tests done within the year.

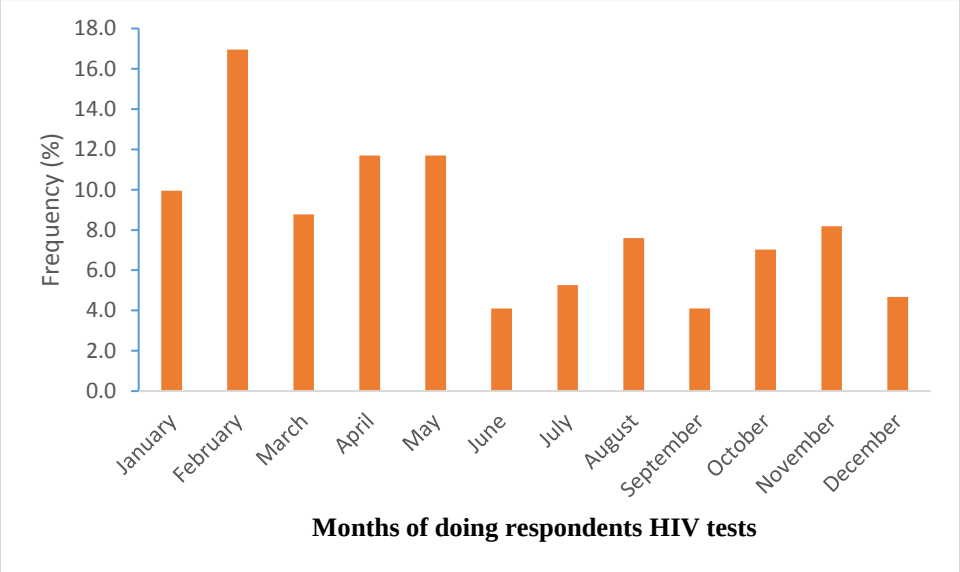

Figure 21: Number of respondents' HIV tests done in 12 months

CHAPTER FIVE: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Discussion

The study assessed three adherence levels to include the following; adherence to intake of PrEP pills, adherence to time of taking PrEP pills and adherence to scheduled clinic appointments. It also demonstrated determinants that influenced adherence levels to oral PrEP among the seronegative partners in HIV discordant heterosexual relationships attending CCC at Mbagathi Hospital.

5.2 Demographic factors

Most of the respondents were females represented by 52.9% and males at 47.1%. This contradicted observation made by Heffron et al., (2012) that in sub Saharan Africa the majority of index case of serodiscordant couples are believed to be more men than women. The study demonstrated that 53% of women in heterosexual HIV discordant relationship were seropositive hence they are likely to have equal chances like men to have seropositive status in serodiscordant couples. This observation was similar to a finding of a cohort of 27 groups with a total of 13,061 couples and demographic health survey data of 1,145 couples in 14 countries of sub Saharan Africa which showed 47% of women in heterosexual HIV discordant relationship were seropositive (Eyawo et al., 2010).

A big proportion of the respondents had Primary level of education (39.2%), followed by those with Secondary level of education (31.4%), College (23.5%) and few with University level of education (5.9%). The study participants who were self-employed represented a bigger proportion (56.9%), followed by the unemployed (23.5%) and employed (19.6%). This was attributed to the big catchment population of the clinic being Kibra slums with majority in informal employment.

Most of the respondents (38%) were within the age bracket of 30-39 years, followed by age bracket of 40-49 years (30%), 20-29 years (24%), 50-59 years (6%) and over 60 years (2%). Having a bigger proportion of the respondents being in their reproductive age of between 30-39 years (38%), contributed to a small proportion (7.7%) seeking PrEP drugs in order to conceive and bring forth their own HIV uninfected children.

Males were 1.009 times more likely to adhere to PrEP medication than females and paradoxically females are known to seek more medical attention and adhere to medical advice than males. Increase in age and education level were associated with an increased likelihood to adhere to PrEP medication. Employment status did not significantly influence adherence, which was attributed to the fact that all the CCC services are offered for free, so there were no major financial challenges encountered when accessing the PrEP services. This was contrary to observation made from a study done at Kilifi and Kangemi on homosexual partners using PrEP, which concluded that participants who had good source of income had a higher adherence than the unemployed participants (Mugo et al., 2015). The finding also contradicted observation made by Zheng et al., (2018) that economic factors have also a role in adherence because it have been shown those clients who are employed have good adherence to oral PrEP than the unemployed ones. Curran et al, (2012) highlighted some of the factors that may influence oral PrEP adherence are age of the couple, number of children and marital status. Desire to have more children did not influence adherence.

5.3 Adherence levels

5.3.1 Adherence to intake of PrEP pills

All the respondents were prescribed Tenofovir (TDF) 300mg and Emtricitabine (FTC) 200mg fixed dose combination which was either dispensed for 1 month or 3 months duration. Majority of

the respondents (89.4%) reported that they were taking their PrEP pills every day and had never missed a single dose while 10.6% had missed a dose. Most of the respondents (74%) reported that they did not occasionally forget to take their PrEP while 26% occasionally forgot to take their pills. Of the respondents who missed their PrEP pills occasionally, 80% missed between 1 to 2 pills per month while 20% missed more than 4 pills in a month. To validate the self-reporting by the respondents after the interview, the investigator assessed all the interviewed respondents' medical records by use of a checklist which assessed adherence status in the medical records. Adherence assessment was completed in majority of respondents' files at 89.6%, where 10.4% were not completed. This secondary assessment of adherence from the respondents' clinic medical records matched with what the respondents had self-reported on their adherence to intake of PrEP pills. The adherence to PrEP pills intake (89.4%) recorded was much higher when compared with the values given by Desai et al., (2017) of more than 70% as having high drug adherence, 41%-70% moderate adherence and less than 40% as low adherence. 80% of the respondents who missed taking their pills, missed between 1 to 2 pills per month against a recommendation by WHO of taking about 4 to 7 doses on average per week which is adequate dose to protect them from acquiring HIV infection during the periods that they were highly exposed to HIV infection (WHO, 2014).

5.3.1.1 Respondents' duration in serodiscordant relationship influence on intake of PrEP pills

The mean length time of being in a serodiscordant heterosexual relationship was 4 years. The study established that the longer the period the discordant partner stayed in their relationship the more adherence to PrEP medication registered, which was as a result of the couple accepting their HIV discordant status and willingness to care and support each other.

5.3.1.2 Influence of giving support during intake of PrEP pills on respondents' adherence to PrEP pills intake

Several support factors were associated with the respondents' adherence to PrEP and had an effect in determining adherence levels recorded. The respondents (56%) who did not use a condom when using PrEP demonstrated good adherence than the respondents who were using PrEP and condom at the same time. This was attributed to the greater risk posed of HIV infection acquisition by the individuals who were using PrEP only, if they did not exercise good adherence to treatment. This showed a similarity with some studies which were done in USA that demonstrated individuals in HIV discordant heterosexual relationship did not embrace correct and consistent use of condoms hence putting the HIV negative individual in these relationships into more risk of contracting HIV infection from the HIV positive partner (McMahon et al., 2014). However this contradicted a finding from a study done in Kenya, a site at Thika that analyzed 96 HIV uninfected individuals sexual behavior change and adherence to PrEP which observed that there was no correlation of unprotected sex with PrEP use (Curran et al., 2012). The respondents (90.2%) who involved their partner in making decision on using PrEP medication were found to have less adherence to PrEP however the respondents (80%) that engaged their partners in adherence support and had a plan of remembering to take their PrEP pill were found to have good adherence to PrEP. This was attributed to good sensitization on use of PrEP by the health care providers.

5.1.3.3 Effect of respondents behavioral factors on adherence to PrEP pills intake

Majority of the respondents (80.4%) did not take breaks from taking PrEP medication while some respondents (19.6%) reported to have taken PrEP breaks. Most of respondents (72%) engaged in protected sex after they stopped taking PrEP medication. Majority of the respondents (96%) had a HIV test done after every 3 months. Therefore respondents who engaged in protected sex (used

condoms) after taking a break from use of PrEP and those who had a HIV test done frequently, registered high adherence to PrEP medication attributed from the motivation of remaining HIV uninfected.

5.1.3.4 Side effects experienced after administration of PrEP medication and their influence on adherence to intake of PrEP pills

Most of the respondents (58.3%) experienced side effects after using PrEP medication for the first 3 months. Some of the respondents (30.8%) taking PrEP medication experienced headaches, followed by nausea (17.3%), dizziness (9.6%) among many other side effects that were reported. Increase in chance of encountering a side effect was associated with a reduction in adherence to PrEP medication. The same scenario was registered by a study done at Thika which demonstrated willingness of taking PrEP drugs by HIV uninfected individuals in serodiscordant sexual relationship, 90% of them indicated they were willing to take PrEP on long term basis, however side effects experienced when taking PrEP drugs was their main concern (Heffron et al., 2012). WHO, (2014), in a meeting to address PrEP adherence highlighted side effects as one of the factors that deter good adherence, hence some clients may opt out completely from the oral PrEP program or reduce their adherence levels especially when the adverse effects are severe.

5.1.3.5 Attitude of the respondents towards PrEP use and their influence on intake of oral PrEP

Majority (98.0%) of the respondents stated that oral PrEP was used for prevention of HIV infection acquisition by the seronegative partner from the infected partner during sexual intercourse and 2% of respondents indicated it is used by serodiscordant couples to conceive when one partner is HIV positive to prevent HIV infection. Most of the respondents (73.1%) stated that using PrEP had benefited them by being safe from acquiring and getting HIV infection, 9.6% stated PrEP had helped them to enjoy unprotected sex with their HIV infected partner, 7.7% stated PrEP had helped

them to conceive and remained HIV negative, 7.7% stated it had helped them to sustain their marriage and 1.9% stated they had improved confidence of remaining protected from getting HIV infected.

Attitude factors were assesed to determine their association with adherence to PrEP medication. Most of the respondents (73.5%) who showed they had knowledge on PrEP and those who demonstrated confidence in PrEP safety in prevention of HIV infection (70.3%) were found to have good adherence to PrEP medication. Those respondents who stated they encountered challenges when refilling PrEP were found to have less adherence to PrEP.

5.1.3.6 Social factors that influenced respondents' adherence to intake of PrEP pills

Majority of the respondents did not have any sexual partner outside their marital partners (88.2%) while 11.8% had sexual partners outside their marital partners. The number of sexual partners outside marital partners stated was 1. All individuals who had extra marital affairs stated that they knew the HIV status of their sex partners. A small group of the respondents (19.6%) took alcohol or any other substance that affects mental judgement while 78.4% reported that they did not take alcohol or any other substance of abuse. Having a sexual partner outside marital partner and taking alcohol or other factors that impairs judgement significantly reduced adherence to intake of PrEP pills. These results were congruent with Curran et al, (2012) who highlighted lifestyle factors like excess alcohol intake, injectable drug abuse, multiple sexual partners, engaging in transactional sex are all attributed with increased HIV infection since some may interfere with the intellect judgement when engaging in sex and also reduce adherence to PrEP drugs.

5.3.2 Adherence to time of PrEP pills intake

Adherence of consistency in time of taking oral PrEP was assessed and majority of the respondents (96%) were consistent with their time of taking PrEP. Most of the respondents (58%) took PrEP at 9pm, 20% took at 10pm and 12% at 8pm.

5.3.3 Adherence to scheduled clinic appointments

Majority of the respondents (80%) stated they did not miss their clinic appointments while 20% missed some of their appointments. Validation of adherence to scheduled appointments was assessed from the respondents' medical records. Out of 11 respondents who had missed their scheduled clinic appointments 81.1% had missed one appointment while 18.2% had missed two appointments. However missing clinic appointments was found not to significantly influence adherence to PrEP medication (p value=0.65). Despite some respondents missing their clinic appointments they did not miss their PrEP pills attributed to the respondents getting extra pills enough to cover them for some days in case they did not make to the clinic on the scheduled appointment day. Other respondents preferred coming early to the clinic to refill their PrEP before their scheduled appointment if the appointment day coincided with the days they had other engagements. This demonstrated flexibility of the health care providers in service provision which contributed to the high overall PrEP adherence levels recorded in the clinic. It also ensured that all the clients felt cared for and were accommodated in facilitation of meeting their different daily engagements which also boosted confidence with the clinic's services hence improving overall PrEP adherence.

Checklist assessment of clinic appointments from the respondents' files revealed that, the only baseline laboratory investigations done to only three respondents were liver function test (16.7 %) and hepatitis B and C screening (33.3%). Lack of baseline investigations could be a potential risk

of missing adverse effects to PrEP drugs especially from TDF which can impair the renal function. The HIV status of all the 51 respondents remained negative, with nil sero conversion reported.

The study used self-report method from the respondents to inform on adherence levels. Despite the obvious bias in self-reporting, it remains the most efficient, fast and cost effective method of monitoring oral PrEP adherence (WHO, 2014).

5.4 Limitations of the study

The adherence assessment and determination of adherence levels relied on self-report of the respondents, hence the investigator could not verify whether what the respondents said was true or not. The two weeks data collection time was not sufficient to get all the 51 respondents through convenience sampling because they had appointments spread out throughout the entire year with at least 3 months review time. This made the investigator to call the respondents who were booked in the clinic's PrEP diary yet their appointments were not due to come for interviews sessions in the clinic hence inconveniencing them by coming to the clinic before their appointment dates were due. There was also financial limitation in the budget allocated for the entire study.

5.5 Conclusions

The overall adherence for the different levels (intake, timing, and appointments) was over 70% minimum requirement WHO categorization of having good adherence to oral PrEP. The key determinants of the adherence observed were being a male, being older in age, having higher education, longer period of being in discordant status, receiving partners support, use of condom after PrEP break, use of reminders (alarm) and higher frequency of HIV testing. However side effects, alcohol use and extra marital sex were associated with low adherence across all levels.

5.6 Recommendations

1. The oral PrEP enrollment package should include laboratory monitoring services so as to ensure quality care and continued patient evaluation for any known complications of treatment. Therefore the hospital administration should negotiate with the PrEP program sponsors to support the cost of all laboratory investigations in all the clients taking oral PrEP in the clinic.
2. The positive determinants of good adherence should be upheld and negative determinants should be addressed. In management of these clients there is need to look out for determinants that promote adherence that include maturity in age, being a male, level of education, use of reminders like alarm, frequency of HIV testing, condom use after PrEP break, length of being in discordant status and partners support. Programs should be initiated to create awareness on the effects of bad social habits like alcoholism and extra marital affairs.
3. The NASCOP campaigns towards HIV prevention and use of oral PrEP should equally target both males and females population in the country, rather than the current trend of campaigns which targets males more than females.
4. Further research is needed to explore why men were more likely to have more adherence to intake of oral PrEP than females and the influence of health care providers to overall adherence to PrEP services.

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APPENDICES

APPENDIX I: CONSENT FORM

To be read and interpreted in a language that the respondent is fluent in.

Title of the study: Determinants of Adherence Levels to Oral Pre-Exposure Prophylaxis among Seronegative Partners in HIV Discordant Heterosexual Relationships Attending Comprehensive Care Centre at Mbagathi Hospital.

Institution:

Department of Medical Surgical Nursing, School of Nursing, University of Nairobi, P.O BOX 30197-00400, Nairobi.

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Supervisors:

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University of Nairobi.

Angeline C. Kirui,
Lecturer, School of Nursing Sciences,
University of Nairobi.

Ethical approval: Permission is requested from you to enroll in this medical research study. You should understand the following general principals in a medical research.

Introduction:

I am a student currently pursuing my Masters Degree in Medical Surgical Nursing at the University of Nairobi. I am undertaking a study looking at Determinants of Adherence Levels to Oral Pre-Exposure Prophylaxis among Seronegative Partners in HIV Discordant Heterosexual Relationships Attending Comprehensive Care Centre at Mbagathi Hospital. One of the objectives of being started on Pre-exposure Prophylaxis (PrEP) medication is to prevent HIV infection of the HIV negative partner in a HIV serodiscordant heterosexual relationship. Good adherence is important for the PrEP drugs to be effective in prevention of HIV infection acquisition by the HIV negative partner when engaging in sexual intercourse with a HIV positive partner without use of condoms.

You will be requested to participate in an interview guided by a structured questionnaire that informs your adherence to PrEP drugs. The interview will take around 15-20 minutes. The information obtained from you will then be aggregated to inform about your overall factors that influence your adherence to PrEP medication. Your level of adherence to PrEP drugs will also be determined.

Purpose of the study: The main objective of the study is to establish levels and the factors influencing PrEP medication adherence by HIV negative partners in HIV serodiscordant heterosexual couples.

Procedure to be followed: With your permission, I will interview you using a questionnaire seeking to find out your demographic details and PrEP medication adherence related information.

Risk: There will be no risk involved in this study as there is no new intervention given to you apart from the interview.

Benefits: There will be no direct benefits to you but the findings will be useful in improving the quality of service offered to you as it will inform factors contributing to PrEP adherence and establish adherence levels to PrEP drugs. These will inform and contribute to policy development.

Assurance of confidentiality: All information obtained from you will be kept in confidence. At no point will your name be used or mentioned during data handling or in any resulting publications. Serial number will be used instead.

Your rights as a participant

1. Your agreement to participate in this study is voluntary.
2. You may withdraw from the study at any time without necessarily giving a reason for your withdrawal.
3. After you have read the explanation please feel free to ask any questions that will enable you to understand clearly the nature of the study.

Contacts

In case you need to contact me, my academic department or the Kenyatta National Hospital/University of Nairobi Ethics and research committee concerning this study use the contacts provided below.

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KIAMBATISHO I: FOMU YA IDHINI

Inafaa kusomwa na kutafsiriwa katika lugha ile mhojiwa anaelewa.

Kichwa cha utafiti. Maamuzi Inayosababisha Viwango vya Kukubaliana na Prophylaxia ya Kuzuia Virusi vya Ukimwi kwa Wapenzi Wenye Hawana Virusi vya Ukimwi Lakini Wapenzi wao Wako Na Virusi vya Ukimwi ambao Wanahudhuria Kituo cha Huduma cha Hospitali ya Mbagathi.

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.

Maadili kibali: Naomba ruhusa kutoka kwako kujiandikisha katika utafiti huu. Lazima uelewe kanuni zifuatazo kwa ujumla katika utafiti wowote wa matibabu.

Utangulizi: Mimi ni mwanafunzi sasa anayesomea Masters katika Uuguzi wa Matibabu katika Chuo Kikuu cha Nairobi. Mimi ninafanya utafiti wa Maamuzi Inayosababisha Viwango vya Kukubaliana na Prophylaxia ya Kuzuia Virusi vya Ukimwi kwa Wapenzi Wenye Hawana Virusi vya Ukimwi Lakini Wapenzi wao Wako Na Virusi vya Ukimwi ambao Wanahudhuria Kituo cha Huduma cha Hospitali ya Mbagathi.

Moja ya malengo ya kuanzishwa kwenye dawa ya Pre-exposure Prophylaxis (PrEP) ni kuzuia maambukizi ya virusi vya ukimwi kwa mpenzi asiye na virusi vya ukimwi katika uhusiano wa mapenzi ya mwanamke na mwanaume aliye na virusi vya ukimwi. Ufuatiliaji mzuri ni muhimu kwa dawa za PrEP kuwa na ufanisi katika kuzuia upatikanaji wa maambukizi ya virusi vya ukimwi na mpenzi asiye na virusi vya ukimwi wakati akifanya ngono na mpenzi aliye na virusi vya ukimwi bila kutumia kondom.

Utatakiwa kushiriki katika mahojiano unaongozwa na dodoso iliyojenga ambayo inathibitisha kuzingatia dawa zako za PrEP. Mahojiano itachukua karibu dakika 15-20. Taarifa iliyopatikana kutoka kwako itajumuisha kuhusu mambo yako yote ambayo yanaathiri uzingatifu wako kwa dawa za PrEP. Kiwango chako cha kuzingatia dawa za PrEP pia kitaamuliwa.

Kusudi la utafiti: Lengo kuu la utafiti ni kuanzisha viwango na sababu zinazoathiri kuzingatia dawa za PrEP na washirika wasiokuwa na virusi vya ukimwi.

Utaratibu wa kufuatiwa: Kwa idhini yako, nitakuuliza mahojiano kwa kutumia dodoso la kutafuta kujua maelezo yako ya idadi ya watu na maelezo ya kuambatana na dawa ya PrEP.

Hatari: Hakutakuwa na hatari katika utafiti huu kwa sababu hakuna uingilizi mpya unaopewa mbali na mahojiano.

Faida: Hakutakuwa na manufaa ya moja kwa moja kwako lakini matokeo yatakuwa na manufaa katika kuboresha ubora wa huduma inayotolewa kwako kama itajulisha sababu zinazochangia kuzingatia PrEP na kuanzisha viwango vya kuzingatia dawa za PrEP. Hizi zitajulisha na kuchangia katika maendeleo ya sera.

Uhakikisho wa siri: Taarifa zote zilizopatikana kutoka kwako zitahifadhiwa kwa ujasiri. Hakuna pahali ambako jina lako litatumiwa au kutajwa wakati wa utunzaji wa data au katika machapisho yoyote yanayosababisha. Nambari ya serial itatumiwa badala yake.

Haki zako kama mshiriki.

1. Makubaliano yako ya kushiriki katika utafiti huu ni kwa hiari.
2. Unaweza kujiondoa kwenye utafiti wakati wowote bila lazima kutoa sababu ya uondoaji wako.
3. Baada ya kusoma maelezo tafadhali jisikie huru kuuliza maswali yoyote ambayo itawawezesha kuelewa wazi hali ya utafiti.

Mawasiliano

Kama unahitaji kuwasiliana na mimi, idara yangu ya kitaaluma au Kenyatta National Hospital / Chuo Kikuu cha Nairobi Maadili na kamati ya utafiti kuhusu utafiti huu hutumia mawasiliano yaliyotolewa hapa chini.

Samuel Mwangi Mwaura,

Idara ya Uuguzi wa Matibabu,

Shule ya Uuguzi, Chuo Kikuu cha Nairobi

P.O. Box, 23541-00100. Simu ya Mkono: 0721-825645

Eve Rajula,

Mhadhiri, Shule ya Sayansi ya Uuguzi,

Chuo Kikuu cha Nairobi.

P.O. Box 19676 Nairobi. Tel: 020 4915077

Angeline C. Kirui

Mhadhiri, Shule ya Sayansi ya Uuguzi,

Chuo Kikuu cha Nairobi.

P.O. Box 19676 Nairobi. Simu: 020 4915077

Prof. Anastasia Guantai

Mwenyekiti,

Kenyatta National Hospital / Chuo Kikuu cha Nairobi Kamati ya Maadili na Utafiti,

P.O Box 20723 00202 Nairobi. Simu 020-726300-9 Ext 44355, 44102

CONSENT FORM

DETERMINANTS OF ADHERENCE LEVELS TO ORAL PRE-EXPOSURE PROPHYLAXIS AMONG SERONEGATIVE PARTNERS IN HIV DISCORDANT HETEROSEXUAL RELATIONSHIPS ATTENDING COMPREHENSIVE CARE CENTRE AT MBAGATHI HOSPITAL.

I …… give consent to the investigator to interview me and use the information obtained from me in his study. The nature of the study has been explained to me by Samuel Mwangi Mwaura.

Signature …… Date …….

I confirm that I have explained the nature and effect of the study.

Signature …….. Date ……..

FOMU YA IDHINI

Maamuzi Inayosababisha Viwango vya Kukubaliana na Prophylaxia ya Kuzuia Virusi vya Ukimwi kwa Wapenzi Wenye Hawana Virusi vya Ukimwi Lakini Wapenzi wao Wako Na Virusi vya Ukimwi ambao Wanahudhuria Kituo cha Huduma cha Hospitali ya Mbagathi.

Mimi ..... nimepeana idhini kwa mtafiti kuuliza mimi maswali na kutumia habari kupatikana kutoka kwangu katika utafiti wake. Hali ya utafiti nimeelezewa na Samuel Mwangi Mwaura.

Signature..... Tarehe.....

Ninahakikisha kwamba Nimeelezea asili na athari za utafiti.

Signature .....Tarehe.....

APPENDIX II: PARTICIPANT'S QUESTIONNAIRE

This questionnaire forms part of a Masters of Science in Nursing (Medical Surgical) degree project on Determinants of Adherence Levels to Oral Pre-Exposure Prophylaxis among Seronegative Partners in HIV Discordant Heterosexual Relationships Attending Comprehensive Care Centre at Mbagathi Hospital.

The principal investigator is Samuel Mwangi Mwaura currently a postgraduate student at the department of Medical Surgical Nursing, School of Nursing University of Nairobi.

The information collected will be treated with utmost confidentiality and at no time will you be required to identify yourself by name.

In order to participate you must be a registered HIV negative partner in serodiscordant heterosexual relationship at Mbagathi Hospital Comprehensive Care Centre.

INSTRUCTIONS

It is assured that the data provided by you shall be used only for ascertaining and evaluating Determinants of Adherence Levels to Oral Pre-Exposure Prophylaxis among Seronegative Partners in HIV Discordant Heterosexual Relationships Attending Comprehensive Care Centre at Mbagathi Hospital.

The data collected and the identity of the respondent will be kept confidential.

1. You will have a short interview session of about 15-20 minutes, you will be asked some questions by the investigator, who will record your responses on the questionnaire.
2. All questions carry weightage. Please answer all questions asked. In case a question is not applicable to you, kindly inform the investigator.

3. Answer all the questions truthfully, in case any of the question is not clear to you, request the investigator for further clarification on the question.
4. The information gathered concerning your adherence is not punitive in any nature and it will not interfere with your rights of receiving further services and management in the clinic.
5. The questionnaire contains different type of questions:
    a. Sociodemographic data.
    b. Clinical information.
    c. Adherence information.

PARTICIPANT'S QUESTIONNAIRE

Serial number: …… Date ……/……/2019

PART ONE: Demographic profile

1.1 Sex of the respondent:

1 = Male

2 = Female

1.2 Age in years

…….

1.3 Education level

1 = None

2 = primary

3 = Secondary

4 = College

5 = University

1.4 Job cadre

1 = Employed

2 = Self employed

3 = None

PART TWO: Parity factors

2.5 No of children

……

2.6 Do you desire to have more children?

1 = Yes

2 = No

2.7 If Yes above, how many?

…….

ALL PARTICIPANTS WILL NEED TO ANSWER ONE BASIC QUESTION:

'ARE YOU IN A HIV SERODISCORDANT HETEROSEXUAL RELATIONSHIP?' AFTER WHICH THEY WILL CONTINUE WITH OTHER PARTS OF THE QUESTIONNAIRE

Are you in a HIV serodiscordant heterosexual relationship?

1 = Yes -> Move to part three of the questionnaire

2 = No

<u>PART THREE: Behavioral factors</u>

3.1 How long have you been in the HIV serodiscordant heterosexual relationship?

……

3.2 What is your current HIV status?

1= Negative

2 = Positive

If HIV negative move to Part Four

3.3 If you are HIV positive are you currently taking antiretroviral (ARVs) drugs?

1 = Yes

2 = No

3.4 What is your last viral load count level?

1 = undetectable

2 = ≤ 1000

3 = ≥ 1000

3.5 If No in 3.3 what is preventing you from taking ARVs?

……

……

……

3.6 What is your partner's current HIV status?

1 = Negative

2 = Positive

PART FOUR

4.1 Have you ever taken PrEP medication?

1= Yes

2 = No

4.2 If Yes move to Part Five

4.3 If No, what has prevented you from taking oral PrEP as a prevention method if your sexual partner is HIV positive?

……

……

……

PART FIVE

5.1 How long have you taken PrEP medication?

……

5.2 What made you start taking PrEP?

……

……...

5.3 When taking PrEP drugs do you use condoms when engaging in sexual intercourse with your partner?

1 = Yes

2 = No

5.4 Do you use any other family planning method apart from condom?

1 = Yes

2 = No

5.5 If Yes in 5.4 above, which family planning method do you use?

……

5.6 Do you take your pill of PrEP every day without missing?

1 = Yes

2 = No

5.7 What time of the day do you take your PrEP pill? Is the time consistent?

…….

5.8 Do you occasionally forget to take your PrEP pill?

1 = Yes

2 = No

5.9 If Yes in 5.8 above, how many pills do you miss in a week?

1 = 1-2 pills

2 = 2-4 pills

3 = > 4 pills

5.10 When you miss to take your pill, what action do you take?

…….

……..

5.11 How long did you take the PrEP drugs before engaging in sex without condom?

1 = ≤ 7 days

2 = ≥ 7 days

5.12 When you are unable to take PrEP on a daily basis, do you use other HIV prevention methods during that time?

1 = Yes

2 = No

5.13 If Yes in 5.12, which method of HIV infection prevention do you use?

……

……

5.14 Did you involve your partner in making the decision of using PrEP medication?

1 = Yes

2 = No

5.15 Have you ever disclosed to any other person apart from your partner that you are taking PrEP?

1 = Yes

2 = No

5.16 If Yes in 5.15 above what was their reaction after learning you are taking PrEP drugs?

……..

5.17 What is your plan for remembering to take PrEP pill every day?

……

……

5.18 What are your motivating factors and barriers to consistent pill use?

……

……

……

5.19 Do you engage your partner for adherence support?

1 = Yes

2 = No

5.20 Have you taken a break from taking PrEP medication?

1 = Yes

2 = No

5.21 If Yes in 5.20 above why did you stop?

……

……

……

5.22 Did you engage in protected sex (used a condom) during the time you stopped taking PrEP?

1 = Yes

2 = No

5.23 How often do you have your HIV test done?

……

……..

5.22 Do you adhere to routine HIV testing every 3 months as recommended by your clinician?

1 = Yes

2 = No

5.23 If No in 5.22 above, what prevents you from having the HIV test done every three months?

……

……

PART SIX: SIDE EFFECTS

6.1 Have you encountered any side effects when taking PrEP medication?

1 = Yes

2 = No

6.2 If Yes in 6.1 which side effects did you experience?

……

……

……

6.3 How have the side effects affected your adherence?

……

……

6.4 Is there anything you can do to improve and make the situation better?

……

……

……

6.5 If you are unable to take your PrEP medication regularly, do you still want to continue with PrEP medication?

1 = Yes

2 = No

6.6 If Yes in 6.5, what are the barriers encountered by you that hinders your good adherence to PrEP drugs?

……

……

……

6.7 Which measures can you take to address these barriers?

……

……

……

6.8 If you are unable to take your PrEP medication suggest other HIV prevention method that you will use?

……

……

……

PART SEVEN: ATTITUDE

7.1 What is PrEP in your own understanding?

……

……

……

7.2 How does taking PrEP help you?

……

……

……

7.3 How do you get your PrEP drugs?

……

……

……

7.4 When you are not near your registered clinic how do you refill your PrEP drugs?

……

……

……

7.5 What kind of challenges do you encounter in the clinic when refilling your PrEP drugs?

……

……

……

7.6 Do you miss your clinic appointments?

1 = Yes

2 = No

PART EIGHT: SOCIAL FACTORS

8.1 Do you have any other sexual partner outside your marital partner?

1= Yes

2 = No

8.2 If Yes in 8.1 above, how many sexual partners do you have?

……

……

8.3 In 8.2 above, do you know the HIV status of your other sexual partners?

1 = Yes

2 = No

3 = I know HIV status of some partners

8.4 Do you use condoms when engaging in sex with other sexual partners in 8.2 above?

1 = Yes

2 = No

3 = I use condoms sometimes

8.5 In a month, how many times do you have sex with your partner?

1 = 0

2 = 1-5

3 = 6 -10

4 = 11-15

5 = > 15

8.6 Do you take alcohol or any other substance that affects your mental judgment?

1 = Yes

2 = No

8.7 If Yes in 8.6, what do you use?

……

……

8.8 Do you remember to take your PrEP pill after using the substance mentioned in 8.7 above?

1 = No

2 = Yes

3 = I sometimes forget

Thank you for your time and participation in this interview.

APPENDIX III: CHECKLIST FOR EXTRACTING DATA FROM MEDICAL RECORDS/DATABASE

1. SERIAL NUMBER: ……

   AGE (years) ……

   SEX …….

2. Date of registration at Mbagathi Hospital CCC

   ……

3. HIV status

   ……..

4. Date last tested for HIV

   ……..

5. Baseline investigations done

   ……

   ……

   ……

   ……

   ……

6. PrEP medication prescribed, indicate dose, frequency & duration

……

……

……

……

7. Indication for PrEP prescription

……

……

8. PrEP commencement date

……

9. HIV status at 3 months after PrEP commencement.

……

10. Side effects reported

……

……

……

11. Number of missed appointments

……

……

12. Assessment of PrEP adherence

……

……

……..

12. Defaulters counselling status

……

…….....

13. STI screening

……....

……

14. Condom use

……

……

15. Number of HIV test done in 12 Months and dates done

……

……

……

16. Seroconversion status

……

APPENDIX IV: RESULTS DUMMY TABLES/FIGURES

Social-Demographic Dummy Table

PARAMETER	CHARACTERISTIC	FREQUENCY	PERCENTAGE
Gender	Male		
	Female		
	Total		
Age in years	< 20		
	20-29		
	30-39		
	40-49		
	50-59		
	>60		
	Total		
Education level	None		
	Primary		
	Secondary		
	College		
	University		
	Total		
Employment status	None		
	Self employed		
	Employed		
	Total		

Adherence levels - Number of oral PrEP pills missed per week

Pills missed per week	Frequency	Percentage
None		
1-2 pills		
2-4 pills		
>4 pills		
Total		

Number of HIV negative partners in HIV discordant relationships

Gender	Frequency	Percentage
Male		
Female		
Total		

Knowledge on the meaning and importance of oral PrEP

Responses	Frequency	Percent
Correct		
Not correct		
Total		

Relationship between gender and knowledge on oral PrEP

Gender	Had the knowledge	Lacked knowledge
Male		
Female		
Total		

Side effects reported when taking oral PrEP

Characteristic	Frequency	Percentage
None		
Moderate		
Severe		
Total		

Duration in serodiscordant relationship

Number of years	Frequency	Percentage
<1		
2-5		
6-10		
11-15		
16-20		
21-25		
>30		

Behavioral/social factors affecting adherence

Parameter	Status	Frequency	Percentage
Missed appointments of clinic	Yes		
	No		
Have other sexual partner	Yes		
	No		
Condom use with other sexual partners	Yes		
	No		
Alcohol/substance abuse	Yes		
	No		
HIV test every three months	Yes		
	No		

Seroconversion status

Gender	HIV seroconversion frequency	Percentage
Male		
Female		
Total		

APPENDIX V: LETTER OFAPPROVAL FROM KNH/UON ERC

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH-UoN ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/ Mod&SAE/234

May 15, 2019

Samuel Mwangi Mwaura
Reg. No.H56/7107/2017
School of Nursing Sciences
College of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 15 MAY 2019 KNH/UoN-ERC P. O. BOX 20723 - 00202 NAIROBI

Dear Samuel

Re: Approval of modifications – study titled "Determinants of Adherence levels to Oral Pre-Exposure Prophylaxis among Seronegative Partners in HIV Discordant Heterosexual Relationships attending Comprehensive Care Centre at Mbagathi Hospital (P84/02/2019)

Your communication dated March 10, 2019 refers.

The KNH-UoN ERC has reviewed and **approved** changes made to the study title from 'Determinants of Adherence Levels to Oral Pre-Exposure Prophylaxis among Seronegative Partners in HIV Discordant Heterosexual Relationships attending Comprehensive Care Centre at Kenyatta National Hospital' to '***Determinants of Adherence Levels to Oral Pre-Exposure Prophylaxis among seronegative Partners in HIV Discordant Heterosexual Relationships attending Comprehensive Care Centre at Mbagathi Hospital'.***

Approval has also been granted to change the study site from KNH-CCC to Mbagathi Hospital CCC in order to acquire the approved sample size within the approved period.

Yours sincerely,

PROF. M.L. CHINDIA
SECRETARY, KNH-UON ERC

c.c. The Principal, College of Health Sciences, UoN
The Director CS, KNH
The Chairperson, KNH-UoN ERC
The Director, School of Nursing Sciences, UoN
Supervisors: Mrs. Rajula Rysper Eve, Mrs. Angeline Kirui

Protect to discover

APPENDIX VI: LETTER OF APPROVAL FROM MBAGATHI HOSPITAL

NAIROBI CITY COUNTY

Tel: 2724712, 2725791, 0721 311 808
Email: mbagathihosp@gmail.com

Mbagathi Hospital
P.O. Box 20725- 00202
Nairobi

COUNTY HEALTH SERVICES

Ref: MDH/RS/1/VOL.1

15th July 2019

Samuel Mwangi Mwaura
UON

RE: RESEARCH AUTHORIZATION

This is in reference to your application for authority to carry out a research on *"Determinants of adherence levels to oral pre- exposure prophylaxis among seronegative partners in HIV discordant heterosexual relationships attending CCC at Mbagathi Hospital."*

I am pleased to inform you that your request to undertake the research in the hospital has been granted.

On completion of the research you are expected to submit one hard copy and one soft copy of the research report / thesis to this office.

15 JUL 2019

Phillip Mibei
For: Chairman – Research Committee
Mbagathi Hospital

APPENDIX VII: Research budget

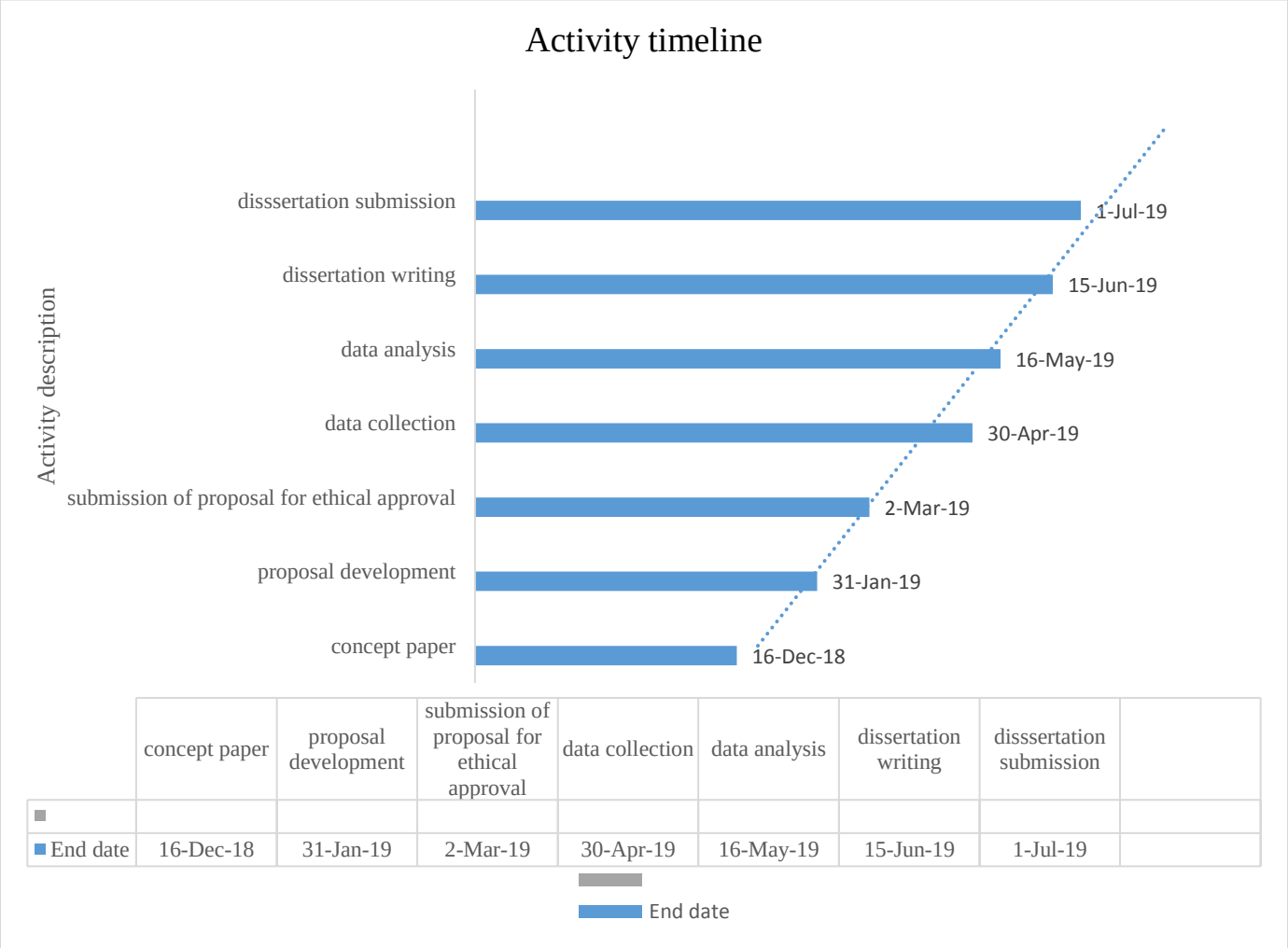
The tabulated cost below constitute the entire budget of the study.

ITEM DESCRIPTION	NUMBER OF ITEMS	COST PER ITEM IN KSHS	TOTAL COST	REMARKS
A. Salaries and wages				
Research assistants stipend	2	10,000	20,000	Will work for 2 months each month paid Kshs 5,000
Statistician	1	20,000	20,000	Data analysis using SPSS for 2 weeks
B. Materials and supplies				
Printing papers	4	500	2,000	4 rims @ cost 500.
Lenovo laptop 500GB	1	25,000	25,000	The laptop will be used by the research assistant for data filtering and entry.
Printing and binding	15	1000	15,000	Printing & binding each copy will cost kshs 1000
Biro pens, rulers, marker pens, envelopes	assorted	2,000	2,000	For use to fill the questionnaires
Telephone airtime	Safaricom/Airtel airtime	2,000	2,000	It will facilitate communication and feedback with research assistant
Internet charges	10 GB	100	1,000	Research assistant will use for sending daily returns on interviews progress
C. Services				
ERC approval	1	2,000	2,000	Research approval charges by the Ethics & Research Committee
Mbagathi Hospital research charges	1	5000	5000	Charges for carrying out a research project at masters degree level
D. Contingency				
Indirect cost	1	6,000	6,000	For any unforeseen cost to be incurred.

Total Cost = KSHS 100,000

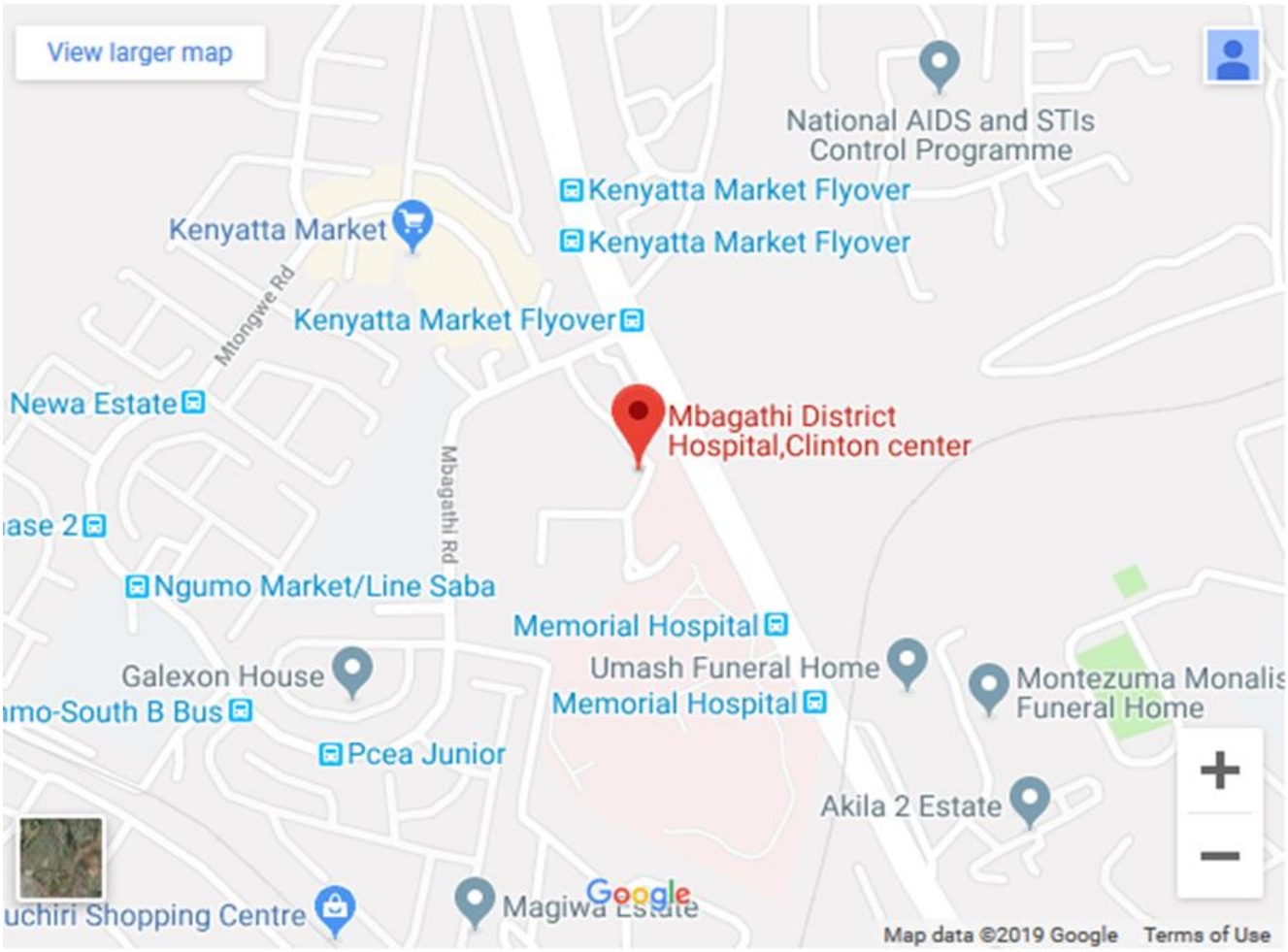
APPENDIX VIII: Activity timeline

The illustrated Gantt chart below describes the timelines used for the entire study period. (Article and Webb, 2013).



	concept paper	proposal development	submission of proposal for ethical approval	data collection	data analysis	dissertation writing	disssertation submission	
End date	16-Dec-18	31-Jan-19	2-Mar-19	30-Apr-19	16-May-19	15-Jun-19	1-Jul-19	

APPENDIX IX: MBAGATHI HOSPITAL GOOGLE MAP



Determinants of Adherence Levels To Oral Pre-Exposure Prophylaxis Among Seronegative Partners In HIV Discordant Heterosexual Relationships Attending Comprehensive Care Centre At Kenyatta National Hosp

ORIGINALITY REPORT

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5	Curran, Kathryn, Nelly R. Mugo, Ann Kurth, Kenneth Ngure, Renee Heffron, Deborah Donnell, Connie Celum, and Jared M. Baeten. "Daily Short Message Service Surveys to Measure Sexual Behavior and Pre-exposure Prophylaxis Use Among Kenyan Men and Women", AIDS and Behavior, 2013. Publication	<1%